radiological health

Radiation Safety in Nuclear Medicine: A Practical Guide

BRH

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

BRH PUBLICATIONS

Publications of the Bureau of Radiological Health (BRH) are available as paper copies from either the U.S. Government Printing Office (GPO) or the National Technical Information Service as indicated by the GPO or PB prefix, respectively, on the ordering number. Publications are also available in microfiche from NTIS at $3.50 per copy. To receive all BRH reports in microfiche, at $0.85 each, you may establish a deposit account with NTIS and request automatic distribution of "FDA/HFX" reports under the "Selected Research in Microfiche" program. Publications without GPO or PB number are available only from BRH, without charge.

Addresses for ordering are: Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 **($1.00 minimum order)**; National Technical Information Service, Springfield, VA 22161 **(outside North America, prices are double those listed)**; and Bureau of Radiological Health, Technical Information Staff (HFX-28), 5600 Fishers Lane, Rockville, MD 20857. All prices are subject to change.

FDA 80-8108 Positive Beam Limitation Effectiveness Evaluation (GPO 017-015-00163-6, $2.00) (PB 80-166937, mf only).

FDA 80-8109 Proceedings of a Workshop on Thermal Physiology (PB 80-187867, $9.50).

FDA 80-8110 Quality Assurance Programs for Diagnostic Radiology Facilities (GPO 017-015-00166-1, $2.50) (PB 80-183338, mf only).

FDA 80-8111 Get the Picture on Dental X Rays (brochure).

FDA 80-8113 Sourcebook - Medical Radiation Materials for Patients (GPO 017-015-00178-4, $2.00).

FDA 80-8116 Chest X-Ray Screening Practices: An Annotated Bibliography (GPO 017-015-00167-9, $3.50) (PB 80-183890, mf only).

FDA 80-8117 X Radiation and the Human Fetus - A Bibliography (PB 80-157712, $20.00).

FDA 80-8118 A Word of Caution on Tanning Booths (brochure).

FDA 80-8119 Measurements of Emission Levels During Microwave and Shortwave Diathermy Treatments (GPO 017-015-00168-7, $1.75) (PB 80-194772, mf only).

FDA 80-8120 Microwave Oven Radiation (brochure) (supersedes FDA 79-8058).

FDA 80-8121 Laser Light Show Safety - Who's Responsible? (brochure).

FDA 80-8122 Microwave Hazard Instruments: An Evaluation of the Narda 8100, Holaday HI-1500, and Simpson 380M (PB 80-227820, $6.50).

FDA 80-8124 Optimization of Chest Radiography - Proceedings of a Symposium Held in Madison, Wisconsin, April 30-May 2, 1979 (GPO 017-015-00176-8, $7.50) (PB 80-208317, mf only).

FDA 80-8125 Research Into the Biological Effects of Ionizing Radiation in The Bureau of Radiological Health (GPO 017-015-00172-5, $4.00) (PB 80-217268, mf only).

FDA 80-8126 Symposium on Biological Effects, Imaging Techniques, and Dosimetry of Ionizing Radiations (July 1980) (GPO 017-015-00175-0, $8.00) (PB 81-112351, mf only).

FDA 80-8128 The Selection of Patients for X-ray Examinations: The Pelvimetry Examination (GPO 017-015-00174-1, $2.00) (PB 81-113490, mf only).

FDA 80-8129 Possible Genetic Damage from Diagnostic X Irradiation: A Review (PB 81-101743, $6.50).

FDA 80-8130 Nationwide Survey of Cobalt-60 Teletherapy: Final Report (PB 81-101784, $9.50).

FDA 80-8131 Vignettes of Early Radiation Workers: A Videotape Series (flyer).

FDA 80-8135 Hazards from Broken Mercury Vapor and Metal Halide Lamps (Notice of Alert) (pamphlet).

FDA 81-8023 Radiological Health Training Resources Catalog 1981 (supersedes FDA 79-8023).

FDA 81-8025 Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM) (PB 81-238842, $9.50).

FDA 81-8027 Directory of Personnel Responsible for Radiological Health Programs (supersedes FDA 80-8027, March 1980).

FDA 81-8033 Bureau of Radiological Health Publications Index (supersedes FDA 79-8033) (PB 81-156192, $18.50).

FDA 81-8034 Report of State and Local Radiological Health Programs, Fiscal Year 1979 (PB 81-167678, $6.50).

FDA 81-8042 CSU-FDA Collaborative Radiological Health Laboratory Annual Report 1979 (PB 81-184566, $15.50).

(HHS Publication FDA 82-8180)

Radiation Safety in Nuclear Medicine: A Practical Guide

Edited by:

Vincent J. Sodd, Ph.D.
Nuclear Medicine Laboratory
Division of Electronic Products

WHO Collaborating Centers for:
- Standardization of Protection Against Nonionizing Radiations
- Training and General Tasks in Radiation Medicine
- Nuclear Medicine

November 1981

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Bureau of Radiological Health
Rockville, Maryland 20857

FOREWORD

The Bureau of Radiological Health develops and carries out a national program to control unnecessary human exposure to potentially hazardous ionizing and nonionizing radiations and to ensure the safe, efficacious use of such radiations. The Bureau publishes the results of its work in scientific journals and in its own technical reports.

These reports provide a mechanism for disseminating results of Bureau and contractor projects. They are distributed to Federal, State, and local governments; industry; hospitals; the medical profession; educators; researchers; libraries; professional and trade organizations; the press; and others. The reports are sold by the Government Printing Office and/or the National Technical Information Service.

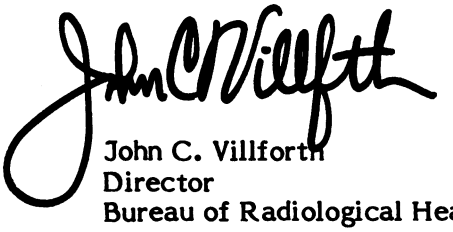
The Bureau also makes its technical reports available to the World Health Organization. Under a memorandum of agreement between WHO and the Department of Health and Human Services, three WHO Collaborating Centers have been established within the Bureau of Radiological Health, FDA:

WHO Collaborating Center for Standardization of Protection Against Nonionizing Radiations;

WHO Collaborating Center for Training and General Tasks in Radiation Medicine; and

WHO Collaborating Center for Nuclear Medicine.

Please report errors or omissions to the Bureau. Your comments and requests for further information are also encouraged.



John C. Villforth
Director
Bureau of Radiological Health

PREFACE

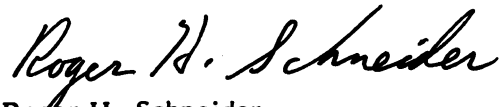
The Division of Electronic Products is the physical science and engineering component of the Bureau of Radiological Health. Within the Division, the Nuclear Medicine Laboratory conducts research, development, and testing of the instrumentation, radiopharmaceuticals, and procedures used in the practice of nuclear medicine. This work supports the general mission of the Bureau to reduce doses and increase the efficiency of utilization of radiation in medicine, and the specific responsibilities for the safety and efficacy of medical devices and provides information and scientific consultation to the Agency's regulatory programs for drugs.

This publication brings together, in concise form, information regarding the many recommendations and requirements for safe operation of a nuclear medicine laboratory. The need for such a compendium was perceived by the staff of the laboratory several years ago. This need arises from several sources. Many individuals enter the field with little training in the handling of radioactive materials; for example, a physician trained in cardiology, oncology, or neurology. The increasing development of portable instrumentation has allowed movement of radiopharmaceuticals from the confines of the nuclear medicine laboratory to coronary and intensive care facilities where personnel may lack adequate knowledge of safe handling procedures. A health physicist, trained to account for all radioactive material placed under his control, may have difficulty adapting to the accepted practice of releasing a patient who has been administered millicurie quantities of radioactivity, with little or no control over subsequent disposal of excreta. Further differences exist between handling practices for radioactive materials in the scientific laboratory and in the medical facility. This guide tries where possible to clarify some of these issues.

An attempt has been made here to provide guidance to existing radiation protection regulations and to further the ideals of radiation protection by keeping radiation exposure as low as practical. This document in no way supersedes the requirements of regulatory authorities. Questions about regulatory requirements should be referred to the appropriate agency.

The guide is divided into ten chapters; each designed to provide the reader with a basic, practical knowledge of an essential topic. A list of references is provided at the end of each chapter. The topics selected span the range of radiological concerns in the nuclear clinic and are not confined to the responsibilities of a particular profession. Therefore, this guide should prove useful to anyone concerned with the practice of nuclear medicine.

In undertaking the task of assembling and editing the guide, Vincent J. Sodd, Ph.D., Director of the Nuclear Medicine Laboratory drew not only on his own able staff but also on the excellent staff of the Eugene L. Saenger Radioisotope Laboratory of the Cincinnati General Hospital, University of Cincinnati, where the Nuclear Medicine Laboratory is located.



Roger H. Schneider
Director
Division of Electronic Products

NOTE

The authors recognize that the currently used radiation units, roentgen, curie and rad, are scheduled for obsolescence. To provide a common set of units for use in all branches of the physical sciences, the International Commission on Radiation Units and Measurements adopted in 1960, the International System of Units (SI). In this System, the curie is replaced by the bequerel (1 Ci = 3.7 x 10^{10} Bq), the rad by the gray (1 rad = 0.01 gray), and the roentgen by coulomb per kilogram (1 roentgen = 2.58 x 10^{-4} coulombs per kilogram). Because the roentgen, curie, and rad are still used by practitioners in nuclear medicine and in the Codes of Federal Regulations pertinent to nuclear medicine, these units have been retained in this document. The conversion factors are given above for those who wish to make the conversion to SI units.

CONTENTS

CONTENTS (continued)

CONTENTS (continued)

CONTENTS (Continued)

1. THE REGULATION OF RADIOACTIVE MATERIALS USED IN MEDICINE

Craig C. Williams
The Eugene L. Saenger Radioisotope Laboratory
Department of Radiology
University of Cincinnati

The manufacture, distribution, possession and use of radiopharmaceuticals in medicine are controlled by a number of Federal, State, and local agencies with overlapping authority. In addition to this regulatory control, there are a number of professional associations and medical insurance programs that exert considerable influence upon the practice of nuclear medicine.

This chapter provides a brief description of the various regulatory agencies primarily concerned with nuclear medicine. References are provided for obtaining the regulations pertaining to nuclear medicine programs. Since these regulations are subject to change, it is important that nuclear medicine personnel review current regulations before establishing or revising nuclear medicine programs. A brief description of other regulatory agencies and the major professional associations involved with nuclear medicine is also included.

1.1 FEDERAL AND STATE CONTROL OF RADIOACTIVE MATERIAL

1.1.1 Nuclear Regulatory Commission

The Nuclear Regulatory Commission (NRC) was established by the Energy Reorganization Act of 1974. This act abolished the Atomic Energy Commission (AEC) and transferred to the NRC all the licensing and related regulatory functions assigned to the AEC by the Atomic Energy Act of 1954. The authority of the NRC is limited to byproduct, special nuclear, and source material, and excludes naturally occurring and accelerator-produced radioactive materials (NARM). Source material is defined as uranium or thorium in any form, while special nuclear material is U-233 or plutonium or uranium enriched with U-233 or U-235. Byproduct material is radioactive material made radioactive by exposure to radiation from the use or production of special nuclear materials and uranium mill tailings.

Sec. 274 of the Atomic Energy Act of 1954, as amended (Public Law 86-373), provided a means for individual States, by agreement with the NRC, to accept responsibility to regulate byproduct, source, and certain special nuclear materials within their jurisdiction, and their regulations are compatible with those of the NRC. A listing of the Agreement States is given in Table 1.1.

The States are responsible for the possession and use of naturally occurring and accelerator-produced radionuclides.

Authorization for the possession and medical use of byproduct material is governed by the following types of licenses:

1. General license for registrant physicians. This authorizes the possession and use of limited quantities of certain prepackaged individual dosages for measurement of thyroid uptake, blood, and plasma volume, intestinal absorption, and red blood cell volume and survival time determinations (except in pregnant patients).

2. General license for in vitro testing. This authorizes physicians, clinical laboratories and hospitals to possess and use small quantities of certain radionuclides for in vitro clinical or laboratory tests not involving the internal or external administration of radioactive material or its radiation emissions to humans or animals.

3. Specific license for individual physicians. This license authorizes individual physicians or groups of physicians to possess and use radionuclides in the licensee's office practice outside of a medical institution.

4. Specific license of limited scope. This license is issued to institutions and authorizes the clinical use of specified radionuclides by physicians with the approval of the institution's medical isotope committee.

5. Specific license of broad scope. This license is issued to qualified institutions and authorizes multiple quantities and types of radionuclides for unspecified users in medical programs operating under the supervision of the institution's medical isotope committee.

Table 1.1 List of States with Type of Radiation Control Program (from CRCPD, 1981)

Licensing States	Registration States	Other States
Alabama*	Alaska	Delaware (issues permit)
Arizona*	Connecticut	District of Columbia (registers radium)
Arkansas*	Hawaii	Montana (registers radium)
California*	Indiana	Puerto Rico (no program)
Colorado*	Iowa	Virgin Islands (no program)
Florida*	Maine	
Georgia*	Massachusetts	
Guam	Minnesota	
Idaho*	Missouri	
Illinois	Ohio	
Kansas*	Oklahoma	
Kentucky*	Utah	
Louisiana*	Vermont	
Maryland*	West Virginia	
Michigan	Wisconsin	
Mississippi*	Wyoming	
Nebraska*		
Nevada*		
New Hampshire*		
New Jersey		
New Mexico*		
New York*		
North Carolina*		
North Dakota*		
Oregon*		
Pennsylvania		
Rhode Island*		
South Carolina*		
South Dakota		
Tennessee*		
Texas*		
Virginia		
Washington*		

*Also an Agreement State

A single byproduct material license is usually issued to cover an instituion's entire byproduct radioisotope program; however, a separate license is required for teletherapy sources, as well as for source and special nuclear materials.

A State radioactive materials license or permit allows the use of naturally occurring and accelerator-produced radionuclides.

The application for a specific license must generally include a description of the radioactive materials needed and their intended uses, as well as the qualifications of personnel and the facilities available. The publication entitled "Guide for the Preparation of Applications for Medical Programs," Regulatory Guide 10.8, 1980 should be obtained from the NRC prior to the completion and submission of an application for a specific license for the possession and use of byproduct material in or on a human being.

If a specific institutional license is obtained, a medical isotope committee must be formed. It is this committee's responsiblity along with the radiation safety office to make sure the license is kept up to date and that the conditions of the license and NRC regulations are followed. Topics covered by these regulations (e.g., radiation safety) are the subject of subsequent chapters of this manual. For a current source of all NRC regulations, a copy of the Code of Federal Regulations, Title 10 (10 CFR), Chapter 1, should be obtained. Revisions of the regulations are incorporated on a yearly basis. Regulations pertaining to the use of byproduct materials are contained in 10 CFR, Parts 19, 20, 30, 35, 71, and 170. The application procedure for any specific license has been simplified by NRC's grouping of various human use procedures into six groups:

Group I covers the diagnostic use of certain prepared radiopharmaceuticals for measurement of uptake, dilution, and excretion studies in patients. A prepared radiopharmaceutical is any byproduct material manufactured in the form to be administered to the patient and labeled, packaged, and distributed in accordance with the manufacturer's license.

Group II covers the use of certain prepared radiopharmaceuticals for diagnostic studies involving imaging and tumor localization.

Group III covers the use of generators and reagent kits for the preparation and use of radiopharmaceuticals in certain diagnostic studies.

Group IV covers the therapeutic use of prepared radiopharmaceuticals that do not normally require hospitalization.

Group V covers the use of prepared radiopharmaceuticals for therapy requiring hospitalization.

Group VI covers the primary use of sealed or encases sources for therapy.

There is a major advantage to these groupings. When the Food and Drug Administration (FDA) approves or exempts a new radiopharmaceutical, it is reviewed by NRC for radiation safety of workers and the general public and then is usually placed in one of the groups and consequently will not require a license amendment before use if a license includes that group. This eliminates much of the need for an institution to amend their license each time a new radiopharmaceutical is approved by FDA. One radiopharmaceutical that was not added to the "groups" was Xenon-133, which requires a license amendment because of its unique radiation handling problems.

1.1.2 State Regulatory Agencies

The extent of regulatory control by a State agency depends on the particular State. Basically, there are three types of radiation control programs for radioactive materials operated by the States. These are Agreement States that license byproduct, source, and special nuclear material; Licensing States that license naturally occurring and accelerator produced radioactive materials (NARM); and Registration States that register NARM. A division of the various States into these three programs is listed in Table 1.1 (CRCPD, 1981). Suggested State Regulations for Control of Radiation were published in 1962 and have been updated as late as October 1978 in cooperation with the Conference of Radiation Control Program Directors, the U.S. Nuclear Regulatory Commission, U.S. Environmental Protection Agency, and U.S. Department of Health, Education, and Welfare. Copies of these suggested State regulations can be obtained from the Bureau of Radiological Health, FDA. These regulations apply to all persons who receive, possess, use, transfer, own or acquire any source of radiation; provided, however, that nothing in these regulations apply to any person to the extent that such person is subject to regulation by the NRC.

1.1.3 Department of Transportation

The Department of Transportation (DOT) is the primary Federal agency controlling safe interstate transport of radioactive materials by rail and by common, contract, or private carrier via public highway, air, and vessel. Their regulations affect the mode by which radiopharmaceuticals are transported. The return of radiopharmaceuticals to the manufacturer or transportation of these agents between offices, labs, and hospitals must, by NRC regulations, meet DOT requirements, except when transported by a physician for his medical practice.

The basic safety requirements that must be met when transporting radioactive materials for human use are adequate containment of the radioactive materials and adequate control of the radiation emitted by the materials.

So that these objectives can be broadly achieved for a wide variety of radionuclides, the radiotoxicity and transport hazard of each radionuclide has been assigned to one of seven transport groups with I being the most hazardous. The radionuclides of general interest to nuclear medicine are in Groups III and IV.

For purposes of assuring the containment of radioactive materials during transport, packaging is classified as follows:

> Type A packaging is adequate to prevent loss or dispersal of a limited amount of radioactive material and maintain the radiation shielding properties for the normal conditions encountered during transport.
>
> Type B and Large Quantity Packaging is designed for quantities of radioactive material greater than Type A limits and is considerably more accident resistant than Type A packaging.

Table 1.2 shows the quantity of radioactivity authorized for each type of packaging. In addition, certain small quantities of radioactive materials are exempt from specified packing, marking, and labeling requirements under the following conditions:

> 1. The materials are packaged so there will be no leakage of contents under conditions normally incident to transportation,
>
> 2. The radiation dose rate at any point on the external surface of the package does not exceed 0.5 mrem/hr,

3. The exterior of the package has no significant removable surface contamination, and

4. The outside of the inner container must bear the marking "Radioactive."

The exempt quantity for each transport group is also shown in Table 1.2.

Table 1.2. Allowable quantities of radioactivity for seven transport groups and special form

Transport group	Quantity limits Type A (Ci)	Type B (Ci)	Exempt (mCi)
I	0.001	20	0.01
II	0.05	20	0.1
III	3	200	1
IV	20	200	1
V	20	5000	1
VI	1000	50000	1
VII	1000	50000	25000
Special Form	20	5000	1

To assure radiation control, packages of radioactive materials are labeled according to one of the three following categories:

Category I; White Label - These packages may be transported with no special handling or segregation from other packages and must have a surface dose rate not exceeding 0.5 mrem/hr.

Category II; Yellow Label - These packages require special handling and have a surface dose rate not exceeding 50 mrem/hr or a dose rate not exceeding 1 mrem/hr at 3 ft from any external surface.

Category III; Yellow Label - These packages have a surface dose rate not exceeding 200 mrem/hr or a dose rate not exceeding 10 mrem/hr at 3 ft from any external surface.

All three label types contain the distinctive trefoil symbol and either one, two, or three bright red stripes. The one-striped label has a white background, while the two- and three-striped labels have a bright yellow background on the upper half of the label and a white lower half.

These regulations are specified in the Code of Federal Regulations, Title 49 (49 CFR), Parts 100-199, and are revised yearly as of December 31. Regulations governing transportation of radioactive materials by rail and by common contract, or private carriers by public highway are in Parts 171-179. Certain "limited" quantities of radioactive materials may also be shipped via mail in accordance with regulations of the U.S. Postal Service (39 CFR 123-125).

1.2 FEDERAL AND STATE CONTROL OF RADIOPHARMACEUTICAL MANUFACTURE

1.2.1 The Food and Drug Administration

As with any new drug, the FDA regulates the manufacturing, distribution, safety and effectiveness of radiopharmaceuticals. This was not always the case because the FDA in 1963 exempted from its regulation radiopharmaceuticals mode from byproduct material as long as the manufacturer followed AEC regulations (28 FR 183, January 8, 1963). Because of the rapidly expanding use of radiopharmaceuticals, the FDA concluded this arrangement was inconsistent with its mandate to determine the efficacy of drugs and removed many of the exemptions in December 1971 (36 FR 21026, November 3, 1971) and later terminated all exemptions thereafter (40 FR 31298, July 25, 1975).

A radiopharmaceutical, therefore, can only be approved for routine clinical use in the United States after approval of the manufacturer's New Drug Application (NDA) by the FDA. When approved, any practitioner authorized by the radioactive material license may, as he deems best for the patient, use the radiopharmaceutical, although it is usually advisable to follow the recommendations specified in the package insert.

A brief description of the two categories of regulations concerning investigational drugs is provided in the Guidelines for the Clinical Evaluation of Radiopharmaceutical Drugs (USDHEW (FDA) 77-3044).

1.2.1.1 Manufacturer-Sponsored Investigations

When a radiopharmaceutical manufacturer sponsors the investigation of new drugs, a "Notice of Claimed Investigations Exemptions for a New Drug" (IND) must be submitted by the manufacturer to the FDA. A practitioner may be accepted as an investigator by the manufacturer only after submission of a "Statement of Investigator," FD Form 1572 or 1573, depending on the extent of the study. The physician is then obligated to follow the protocol specified by the manufacturer, obtain informed consent from each patient, submit patient case report forms to the manufacturer and, in an institution, obtain approval of the institutional review committee and the radiation safety committee. The institution's review committees will ensure that the patient's rights and safety are protected, as well as review the clinical use protocol from a technical standpoint. The membership of the committee, therefore, must be such that it comprehends the nature of the project and the acceptability of the project in relation to institutional regulation, relevant law, standards of professional practice and community acceptance.

1.2.1.2 Physician-Sponsored Investigations

After an approved new drug is shipped in interstate commerce, a physician may elect to use it for an unapproved use. In this situation an IND is not required. If a radiopharmaceutical is shipped in interstate commerce for the purpose of conducting a clinical investigation, an IND (Form 1571) must be filed with FDA. The information submitted must include: the formulation of the drug; laboratory facilities; results from animal or clinical studies, whether published or not; qualifications of the investigators; the protocol to be followed; and an indication that the project has been approved by the appropriate institutional review committee and radiation safety committee.

The IND sponsor is responsible for filing a summary of the progress of his investigations, including adverse reactions, at least annually. All current FDA regulations relevant to filing an IND are published in part 300-499 Code of Federal Regulations, Title 21 (CFR, 1980) which is revised yearly as of April 1.

1.2.1.3 Medical Devices

Since the enactment in 1976 of the Medical Devices Amendments to the Federal Food, Drug, and Cosmetic Act, the FDA has developed and implemented programs to assure the

safety and effectiveness of medical devices. The responsibility for these programs is shared between the Bureau of Medical Devices (BMD) and the Bureau of Radiological Health (BRH). While the BMD is the lead Bureau for most medical devices, the BRH is the lead Bureau in dealing with radiation-emitting medical devices and related accessories. Some medical devices used in nuclear medicine that are regulated by the BRH/BMD include medical accelerators, radionuclide generators, rectilinear scanners, and gamma cameras.

1.2.2 State Regulatory Agencies

The regulatory jurisdiction of the FDA does not extend to the professions of medicine and pharmacy; hence, the appropriate State agency is expected to deal with these professions. Each State licenses individual physicians, nurses, and pharmacists, as well as pharmacies. Presently at least two States are implementing licensure programs for nuclear medicine technologists; however, the State agencies that appear to be the most active in establishing qualifications of personnel in the use of radioactive materials for diagnosis and treatment of disease are the State Boards of Pharmacy. Since model regulations were proposed by the National Association of Boards of Pharmacy in 1977, and the FDA has stated that the appropriate control of nuclear pharmacies belongs with the States (21 USC § 360(g)(1) and 21 CFR 132.51(a)), it is expected that a larger number of States will adopt similar regulations. This will not affect the individual physician in his practice of nuclear medicine if he prepares his own radiopharmaceuticals and should not greatly affect the availability of these agents from existing nuclear pharmacies. An alternative argument is being made by some regulatory bodies, however, that nuclear pharmacies are engaging in the manufacture of radiopharmaceuticals rather than merely the compounding and dispensing of those agents; and hence, should be subject to FDA regulatory control (Robinson, 1976; Halperin, 1978; Halperin, 1980; 40 FR 31314). Although many are still trying to resolve this issue, the NRC's current policy in licensing nuclear pharmacies is to basically hold them to preparation of NDA and IND products if they distribute to "group" medical licensees and not allow inhouse compounding from chemical reagents.

1.3 MISCELLANEOUS CONTROLS

Other organizations affect the practice of nuclear medicine.

The Occupational Safety and Health Administration (OSHA) regulates occupational exposure to radiation not already controlled by the NRC and other hazardous material. The Environmental Protection Agency (EPA) sets Federal guidance for radiation protection including the discharge of radioactive effluents into air and surface water and selection of solid waste disposal sites, as well as guidance for the diagnostic use of radiation in cooperation with the Department of Health and Human Services. The Public Health Service (PHS) regulates and licenses clinical laboratories engaged in interstate commerce. Radiobioassay is considered a technical component of clinical laboratory services (42 CFR 74). The Airline Pilots Association (ALPA) provides guidelines for pilots for acceptance of air shipments of radioactive materials.

The American College of Nuclear Physicians (ACNP), the American College of Nuclear Medicine (ACNM), and the American College of Radiology (ACR) provide guidelines and standards to members concerning the practice of nuclear medicine. Quality assurance guidelines are a part of this effort. The Joint Commission on Accreditation of Hospitals (JCAH) accredits hospitals and health care facilities. JCAH standards cover the organization and staffing of nuclear medicine services, facilities and operations, quality control and safety, and records. Similar standards are maintained for hospital accreditation by the American Osteopathic Association. The College of American Pathologists (CAP) issues standards of practice for laboratory medicine, accredits clinical laboratories and provides a proficiency testing program for subscribers.

Users should be knowledgeable of local ordinances that may affect shipping in or through metropolitan areas or disposal of radioactive materials.

Third party payment insurance programs such as Medicare and Blue Cross specify justifiable procedures and the reimbursible cost. Occasionally reimbursement of investigational procedures is not allowable. This can limit the availability and use of new procedures. Standards for medical services reimbursed by Federal insurance programs of the Social Security Administration are issued by the Health Care Financing Administration of HHS (42 CFR 405).

REFERENCES

Code of Federal Regulations, Title 21 - Food and Drugs (21 CFR). Office of the Federal Register, Washington, D.C. U.S. Government Printing Office (1980).

Conference of Radiation Control Program Directors, Inc. Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM). CRCPD, Published by USDHHS, FDA 81-8025 (1981).

Halperin, J.A. Status Report on Nuclear Pharmacy. In: 9th Annual National Conference on Radiation Control. Meeting Today's Challenges, Seattle, Washington, June 19-23, 1977, pp. 287-289. HEW Publication (FDA) 78-8054 (April 1978).

Halperin, J.A. Regulatory Problems with Radiopharmaceuticals. J Am Pharm NS20, 8:20 (1980).

Notice to Nuclear Pharmacies Regarding the Development of Proposed Regulations and Interim Enforcement Policy. Federal Register (40 FR 31314) (July 25, 1975).

Robinson, R.G. and B.A. Rhodes. Whither Nuclear Pharmacy? J Nucl Med 17:577 (1976).

2. SAFE DESIGN OF NUCLEAR MEDICINE LABORATORIES

Laurence W. Grossman
Nuclear Medicine Laboratory, DEP, BRH, FDA
Cincinnati, Ohio

The underlying philosophy of a well-designed nuclear medicine laboratory is to maintain radiation exposure as low as reasonably achievable while allowing for the smooth and efficient conduct of business within the facility. Voluntary standards and guidelines that address many key aspects of this philosophy have been published by several scientific organizations concerned with radiation safety, including the International Commission on Radiological Protection (ICRP), the International Atomic Energy Agency (IAEA), the National Council on Radiation Protection and Measurements (NCRP), and the World Health Organization (WHO) (ICRP, 1977; IAEA, 1969; NCRP, 1970; Frost, 1975). These documents are addressed to a broad spectrum of radiation sources and users. This chapter will extract those portions of primary interest to clinical nuclear medicine.

Use of most radiopharmaceuticals requires a license for the use of byproduct reactor material from the Nuclear Regulatory Commission (NRC) and/or appropriate State authority, as discussed in Chapter 1. Current license applications require the submission of a scaled or dimensioned laboratory floor plan, noting pertinent radiation protection measures (NRC, 1979). The Joint Commission on Accreditation of Hospitals (JCAH) conducts site visits to nuclear medicine laboratories; testing among other things, the adequacy of design against the following standard (JCAH, 1980):

> "Nuclear medicine services, when provided within the hospital, shall have adequate space and facilities to meet, with safety, the diagnostic and therapeutic needs of the patients."

2.1 FLOOR PLAN FOR A NUCLEAR MEDICINE LABORATORY

The translation of philosophy to working design is never a simple process. Factors including anticipated workload, equipment, the constraints of available space and budget must be factored into each individual design. Model floor plans have been published by several authors (Powsner, 1971; Ingraham, 1966; Frost, 1975). However, the past few years have seen tremendous growth and change in the services provided. The availability of better radiopharmaceuticals with improved imaging properties, combined with advances in instrumentation (e.g., greater sensitivity and resolution), has greatly increased imaging capabilities. The future growth of nuclear medicine facilities will depend upon the improvements made in these areas, but may also be tempered by the impact of alternate imaging modalities that are experiencing similar improvements. Individuals interested in planning a nuclear medicine laboratory can best determine their needs by visiting other facilities with similar attributes. A design can then be formulated based on the successes and failures of others in the field.

A hypothetical floor plan for a diagnostic nuclear medicine laboratory for a medium-sized hospital is shown in Figure 2.1. This plan is only intended to establish perspective and illustrate certain points. The laboratory has space for storage and preparation of radiopharmaceuticals prior to administration, an administration room, three imaging rooms, an uptake measurement room, and a low-level measurements room for quality control and tests of biological samples. Additionally, there are patient waiting areas and office space. As mentioned earlier, differences resulting from such constraints as workload and space will

always be found when comparing an actual laboratory to this one; however, the differences will be primarily in scale and location, rather than function.

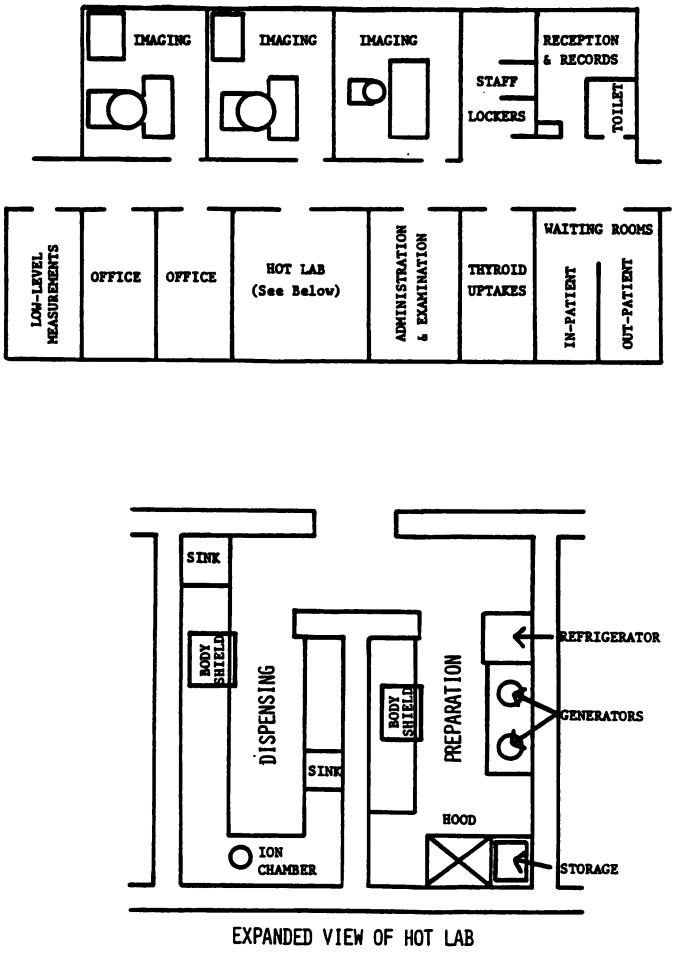


Figure 2.1. Floor plan of a nuclear medicine laboratory in a medium-sized hospital.

It is assumed here that the nuclear medicine service is a separate laboratory. In actual practice, nuclear medicine may be an integral part of radiology or in combination with radiation therapy. In this chapter, attention is restricted mainly to diagnostic nuclear medicine activities although there is some discussion directed toward therapy with unsealed sources.

2.2 CONTROLLED AREAS

Radiation protection principles require a division of space in a nuclear medicine laboratory. Areas are classified as controlled or noncontrolled according to function. The following paragraphs, excerpted from NCRP Publication #39, "Basic Radiation Protection Criteria" (NCRP, 1971), form the basis for this classification:

> "(61) A controlled area is a defined area in which the occupational exposure of personnel to radiation or to radioactive material is under the supervision of an individual in charge of radiation protection. This implies that a controlled area is one that requires control of access, occupancy, and working condition for radiation protection purposes. It also implies control of the escape of radiation beams or radioactive material from controlled areas. In local practice, such terms as 'radiation zone', 'restricted area', or 'radiation area' may be substituted. Areas should not be designated as a 'controlled area' for purposes of permitting relaxation in the degree of

protection of occupants. Every reasonable effort should be made to establish a clear and understood separation between controlled areas and areas, including those under the same management control, in which radiation work is not to be conducted."

"(65) An occupationally exposed individual is one whose work is normally performed in a controlled area, or whose duties involve exposure to radiation and who is subject to appropriate radiation protection controls. A person should not be considered as a radiation worker unless his work necessarily involves the likelihood of radiation exposure."

Areas used for imaging, radiation measurements, radiopharmaceutical preparation, dispensing, or storage are considered to be controlled areas. Areas occupied by secretaries, file clerks, and administrators would not be considered controlled, since these people are not directly involved in the handling of radioactive materials and should not be considered radiation workers. Furthermore, office space for technical personnel, such as physicians, physicists, and chemists, should not be in controlled areas even though these people may be radiation workers, since radiation work is not performed in the office area. Patient waiting areas, because of their ready access to members of the patient's family and the general public should not be considered controlled areas. Areas outside the nuclear medicine laboratory should not normally be considered controlled areas.

For areas designated as "controlled," the actual degree of control should be commensurate with the potential for problems. Operations involving the same degree of control are frequently grouped together. This allows radiation control measures to be most effective while minimizing redundancy. For example, the preparation, dispensing, and storing of radiopharmaceuticals requires a great degree of control because of the large amounts of radioactive material that may be involved in each operation. Space for these operations is frequently grouped together in a single area called the "hot lab," as shown on the floor plan (Figure 2.1).

A nuclear medicine laboratory must conform to all local building codes. In addition, other radiation design safety measures are necessary for the entire controlled area of the laboratory. These are as follows:

1. Control of access and egress. The laboratory should be organized in a way that minimizes worker traffic through controlled areas. Locating the laboratory away from high-traffic corridors is highly desirable. Placement of a receptionist's desk in a strategic location to prevent entry of unauthorized persons is also desirable. Radiation sources of most concern are located almost entirely in the hot lab or storage areas. Outside of these areas, the primary radiation sources are patients themselves. Unauthorized personnel are not allowed in the hot lab area where preparation and dispensing activities present the definite possibility of undetected spills. The use of a continuously operating radiation monitor with an audible alarm in the hot lab indicates the presence of radiation. This provides a useful means of detecting and controlling contamination. When unoccupied, areas containing sources or delicate equipment should be locked.

2. Surface preparation for the occasional, but inevitable spill. Floors, walls, and other work surfaces in controlled areas should be constructed in ways that facilitate easy decontamination in the event of a spill. Floors should be of waxable linoleum or asphalt tile, or an equivalent impervious surface. Walls should be painted with nonporous paint or finished in some other way that allows them to be washed easily. Counter tops should be seamless with a splash guard and constructed of an impervious material. Those counter tops on which unsealed sources may be placed should be covered with absorbent paper with a waterproof backing. Clutter should be minimized.

3. Ventilation for the use of gaseous or volatile radioactive materials. Sufficient ventilation to the outside should be present to maintain airborne radioactive materials, such as I-131 and Xe-133, below accepted limits. This is usually accomplished in the hot lab by working with and storing these materials in an exhaust hood. Areas in which these materials are handled should be under negative pressure with respect to noncontrolled areas to avoid gaseous contamination of noncontrolled areas. Heating and air conditioning systems should be separate for controlled areas and noncontrolled areas.

2.2.1 Hot Lab

Areas within the hot lab are used for radiopharmaceutical preparation, dispensing, and storage. The hot lab may be a single room or a suite of rooms connected together. Radiopharmaceuticals will be handled here in bulk prior to being dispensed into individual doses. Therefore, specific recommendations about access, surface preparation, and ventilation are particularly important. The hot lab should contain radiation monitoring equipment and decontamination materials. There should be ready access to a shower for personnel decontamination, and a sink for disposal of radioactive materials. The sink should be pedal or elbow operated and capable of handling large quantities of water. Actually two sinks are desirable, one for disposing of radioactive solutions, and the other for such tasks as cleaning glassware. Disposal of radioactive waste in a sanitary sewer system is discussed in Section 9.1.2. When activities require frequent movement between rooms of a hot lab, the connecting doors should be propped open or removed.

2.2.1.1 Radiopharmaceutical Preparation Area

At the present time, most nuclear medicine laboratories either use commercially available kits for the preparation of most radiopharmaceuticals or buy ready-to-use preparations from a nuclear pharmacy. Radioactive material, usually Tc-99m, is added to the kit material in a short procedure to make the radiopharmaceutical. Therefore, a counter top with an L-shaped body shield or some equivalent shielding satisfies most needs. Preparations using volatile radionuclides such as I-131 should be done in an exhaust hood equipped with HEPA and/or charcoal filters. Storage space in cabinets or drawers for supplies and a refrigerator for heat sensitive materials should be nearby.

If a facility prepares their own kits from bulk chemicals, then considerably more space will be required for radiopharmaceutical preparation. This may not have a big effect on hot lab requirements because many preparations do not involve handling radioactive materials until the final few steps and could be done, for the most part, outside the hot lab.

2.2.1.2 Dispensing Area

Individual doses ready for administration are prepared in the dispensing area. A shielded counter top, similar to that of the preparation area, is required. The same space could be used for both dispensing and preparation in small facilities, but the separation of these activities greatly reduces the chances of error and is recommended. A sink designed for disposal of radioactivity should be present. At least two radioactive waste containers, preferably covered, are required. One should be for short-lived radionuclides, such as Tc-99m, and another for waste associated with longer-lived materials such as I-131. Refer to Chapter 9 for details of waste disposal.

A second table-top area is required for assay and recording of the dispensed doses. Space for the dose calibrator, record book, and calculator for activity/volume computations is required. Because of the sensitivity of an ion chamber to sources present in the hot lab, the chamber should be located as far from storage areas and other sources in the dispensing area as practical. Distance alone may not be sufficient, and shielding may be necessary for the satisfactory operation of the device.

2.2.2 Storage Area

All nuclear medicine laboratories have need for storage of radioactive materials. Use of one corner of the hot lab for storage is a very common occurrence. However, use of a more remote section of the facility to reduce background and security problems is recommended (ICRP, 1977). It is desirable that the storage area be situated in a way that minimizes the movement of high levels of radioactive material within the establishment. Adequate space should be provided to allow convenient arrangement and segregation of sources, with due regard for their easy identification and removal. During storage, vessels should be placed within a secondary, unbreakable container or tray, large enough to hold their entire contents in the event of breakage or spillage. All items stored should be labeled clearly on the vessel and on the storage container. Individual vial shields or appropriate shielding must be employed, according to the energy and quantity of gamma emissions. The ICRP recommends sufficient shielding so that total leakage radiation for all containers does not exceed 2 mR/hr in any area of the storage room that can be occupied by personnel (ICRP 1977). It also recommends that storage containers shall provide a shielding such that leakage radiation does not exceed 2 mR/hr at a distance of 1 m from the radioactive substance or 20 mR/hr at 5 cm from the outer surface of the protective container. The occupancy of adjacent rooms and the shielding afforded by the intervening walls also need to be considered. The radiation exposure to occupants in adjacent rooms must be kept below permissible levels (NBS, 1954).

Individual vial shields or a cabinet with a 0.32 cm (1/8 in.) lead lining provides adequate shielding for stored Tc-99m pharmaceuticals. Other radionuclides such as I-131 and Ga-67 have gamma emissions more energetic than Tc-99m and require additional shielding. Volatile I-131 is best stored in the exhaust hood behind shielding such as an enclosure of interlocking 5.08 cm (2-inch) lead bricks. Xe-133 is also best stored in the exhaust hood, but only requires shielding similar to that used for Tc-99m. Where only a single hood is available, separate areas within the hood, clearly labeled, should be used for these or similar radiopharmaceuticals and their waste.

Beta emitters such as P-32 should be stored with an inner container of low-Z material such as plastic or glass to minimize bremsstrahlung radiation. The shipping containers of these radionuclides can serve as storage shields. Where refrigeration is required, individual vial shields are easily accommodated in a standard household refrigerator.

When left unsupervised, the storage area must be locked.

2.2.3 Administration Room

The room for diagnostic and therapeutic administrations is frequently an examining room. In the interests of minimizing the movement of unsealed sources, it is convenient to locate the administration room near the dispensing facility.

Therapeutic administrations other than the occasional iodine administration, particularly those with sealed sources, should be performed in a separate facility. Surgical administration will usually be employed for these sources; therefore, it may be most practical to locate the therapeutic administration area in another department of the hospital, such as surgery. When the facility is also used for the administration of high energy sealed sources, the shielding afforded by typical interior walls will probably be inadequate. Constraints of room construction will then be dictated primarily by the use of the sealed sources. Such considerations are beyond the scope of this Chapter. Three sources with recommendations on these matters are ICRP, WHO, and NCRP (ICRP, 1977; Frost, 1975; NCRP, 1970).

2.2.4 Imaging and Uptake Areas

Organ and physiological imaging are the prime functions of a clinical nuclear medicine laboratory. The example laboratory (Figure 2.1) has three imaging rooms. By far the most

common imaging device is the scintillation camera. However, other devices, such as the rectilinear scanner, thyroid uptake probe, and similar specific organ detectors are in use.

It is advisable to provide a separate room, preferably with walls made of dense material (such as concrete, brick, and so forth, rather than plaster board), for each imaging device to reduce the potential for having image interference from radioactive material of another patient. The use of a separate room also maintains patient privacy while minimizing undesirable distractions for both the technologist and the patient.

Room size should be adequate for the imaging device, patient table, spare collimators and several pieces of ancillary hardware, such as computers, tape drives, film imagers, physiological gating devices, and xenon dispensers or traps. Because procedures measuring dynamic function require the administration of racioactive material while in the imaging area, some work space must be available for an administration tray. Additional work space is also needed for the patient's chart, camera log, quality control log, and protocol manual. Space is also needed nearby, if not in the room, for a laundry hamper, a decontamination kit, and a medical emergency cart.

Thyroid uptake measurements are much less demanding in space and equipment. Room for the detector system, patient cot or bed, and a desk or counter for records is all that is required.

2.2.5 Low-Level Measurement Area

Quality assurance of radiopharmaceuticals, tests of biological samples such as for blood volumes, and other measurements of low levels of radioactivity require additional lab space. Because of the sensitivity of radiation counters to background activity, it is best to locate this area outside the hot lab, as far from radiation sources as practical.

The low-level measurement room requires a sink for radioactive disposal and plenty of counter space. The radioactivity levels generally used in this area should be small so that fume hoods and body shielding would not be necessary. Maximum use of all available counter space should be made so that the various functions of the room have as little overlap as possible. This minimizes the chances of contamination from a spill in another testing area.

2.3 NONCONTROLLED AREAS

Areas within the nuclear medicine laboratory where occupational exposure to radiation is not required should be considered noncontrolled areas. Offices, file space, patient waiting areas, and nonradiation laboratory space are examples of such areas. Laboratory design and work activities should be such that exposure levels in noncontrolled areas, from sources located in controlled areas, are appropriate for the general public. Radiation sources should not be brought into or through noncontrolled areas. Space must also be available to handle, in an isolated manner, those inpatients suspected of having contagious diseases.

2.3.1 Patient Waiting Room

At least two separate waiting areas are recommended where workload and space permit; one for more moderately ill patients, and the other for more seriously ill and disabled patients (Frost, 1975; Fischer, 1976). Generally, this amounts to a separation of outpatients from inpatients. Patients with minor complaints and disabilities may be distressed when they see others who are seriously ill, because these occurrences may lead them to think of undesired courses to their own illness. Conversely, very sick patients who need more restful surroundings should not be required to share facilities with moderately ill patients, for the latter may often be inconsiderate of their needs.

Certain diagnostic tests, such as bone scans and brain scans, may require a waiting interval after the administration of activity before imaging begins. The patient will often spend this interval in the waiting area. Among the more seriously ill patients, radiation spills of contaminated urine can result from such problems as loss of bladder control or accidental disconnection of catheter systems. Although these waiting areas are not classified as controlled areas, radiation safety concerns for the ease of cleanup and avoidance of spreading contaminated material must be recognized. Waxable floors, or the equivalent, instead of carpeting, are indicated for ease of decontamination. The presence of two separate waiting areas further reduces problems associated with these spills. Furthermore, because of the possibility of contamination, it is recommended that waiting rooms be located away from unrelated traffic.

2.3.2 Offices

The arrangement of space for such uses as offices, conference rooms, libraries, and recordkeeping will be determined by the needs of the staff. There should be a clear differentiation between this uncontrolled space and the controlled areas such as imaging or uptake rooms and the hot lab.

REFERENCES

Fischer, H.W. Strong Memorial Hospital and the University of Rochester Medical Center. Appl Radiol 5:4,55 (1976).

Frost, D. and H. Jammet. Manual on Radiation Protection in Hospitals and General Practice, Volume 2: Unsealed Sources. WHO, Geneva (1975).

Ingraham, S.C., M. Barnett, and W. Taylor. Radioisotope Facilities in the General Hospital. PHS Publication #930-D-22 (1966).

International Atomic Energy Agency. IAEA Safety Series #30: Manual on Safety Aspects of the Design and Equipment of Hot Laboratories. IAEA, Vienna (1969).

International Commission on Radiological Protection. ICRP Publication #25: The Handling, Storage, Use and Disposal of Unsealed Radionuclides in Hospitals and Medical Research Establishments. Pergamon Press, New York (1977).

Joint Commission on Accreditation of Hospitals. Nuclear Medicine Services: Accreditation Manual for Hospitals. JCAH, Chicago (1980).

National Bureau of Standards. Handbook 59: Permissible Dose from External Sources of Ionizing Radiation. (Also addendum NCRP Report No. 39.) Washington, D.C. Government Printing Office (1954).

National Council on Radiation Protection and Measurements. NCRP Report #34: Medical X-Ray and Gamma-Ray Protection for Energies Up to 10 MeV. NCRP, Washington, D.C. (1970).

National Council on Radiation Protection and Measurements. NCRP Report #39: Basic Radiation Protection Criteria. NCRP, Washington, D.C. (1971).

U.S. Nuclear Regulatory Commission. NRC Regulatory Guide 10.8: Guide for the Preparation of Applications for Medical Programs. NRC, Washington, D.C. (1980).

Powsner, E.R. and D.E. Raeside. Diagnostic Nuclear Medicine, Chapter 7. Grune and Stratton, Inc., New York (1971).

3. PERSONNEL RADIATION EXPOSURE MONITORING

Harley V. Piltingsrud
Nuclear Medicine Laboratory, DEP, BRH, FDA
Cincinnati, Ohio

The use of any radioactive materials in nuclear medicine laboratories produces a possibility that laboratory personnel may be internally or externally exposed to radiations emitted by these materials. Since it is believed that any exposure to ionizing radiations may result in some cumulative harmful effects, great care should be taken in designing the radiation protection program for the laboratory. Thus, through a combination of both proper equipment and procedures, personnel exposure may be kept to the lowest practical level. The health physicist normally attempts to achieve this in the following way:

1. Reducing radiation exposure to personnel, wherever practical, by the proper use of shielding, equipment design, radiation warning devices, safety interlocks, and radioactive material handling procedures.

2. Instituting a program of routine monitoring of direct radiation exposure rates and surface contamination levels in work areas with the proper use of survey instruments.

3. Instituting a program of monitoring the external and/or internal radiation exposure of individuals through the use of bioassay, body counting, and personnel radiation dosimeters.

3.1 INTERNAL DOSIMETRY

Individuals working with radioactive materials may be exposed to radiations emitted by these materials through several pathways. Radioactive materials may enter the body by inhalation, ingestion, and implantation in wounds or other body openings. When this occurs, body tissues are exposed directly to the radiation emitted by the materials. In these instances, an estimate of the radiation dose (or more correctly the radiation dose equivalent) to the individual is generally made. This is normally done by first determining what radionuclides were involved, and then making an estimate of what the quantities of the materials were and how they were distributed in the body. This usually involves a combination of reconstructing the accident, a consideration of the facilities and procedures used in handling these materials, and whole body and/or individual organ counting of the particular radioactive material. Intensive bioassay and whole body counting programs are not usually used in nuclear medicine facilities; however, the need for such programs will be determined by the facility's radiation protection officer in conjunction with the licensing authority. This is determined when a license application is made for the use of radioactive materials in the facility per Title 10 of the Code of Federal Regulations, Part 20.108 (CFR 1980) and/or appropriate State agency.

3.2 EXTERNAL DOSIMETRY

Radioactive materials that remain outside the body produce a significant radiation dose only when the radiation emitted by them has sufficient penetrating characteristics to reach sensitive tissues in the body. Certain types and energies of ionizing radiation cannot penetrate the dead layers of the skin; consequently, they do not need to be considered in external personnel dosimetry. These include most alpha radiation sources, lower energy beta radiation sources, and very low energy (under approximately 5 keV) gamma radiation sources.

In most cases of low level exposure to external sources of ionizing radiation, such as one would receive occupationally in a nuclear medicine laboratory, little or no physical evidence exists after the exposure to determine what dose was received by a particular radiation worker. Yet, a record of the cumulative radiation dose to the worker is very important in order to document that a significant radiation dose has not been acquired by the individual. Such measurements are equally important for use in detecting unusual radiation exposure conditions so that corrective measures can be instituted to prevent significant radiation exposure to the individual.

3.3 PERSONNEL DOSIMETERS

Because of the importance of obtaining information on the cumulative dose in radiation workers, a class of devices referred to as "personnel dosimeters" has been developed and is used almost universally by radiation workers. Personnel dosimeters are devices that, when worn on some portion of the body, will record the radiation exposure to that portion of the body. The record of that exposure may be retrieved by a variety of means depending on the construction of the personnel dosimeter.

Figure 3.1 depicts a direct reading pocket dosimeter. This dosimeter contains an ionization chamber as a radiation sensor. The dosimeter can be read at any time during the period it is being worn by looking through the viewing lens at the end of the barrel and reading the scale behind the hairline indicator.

Figure 3.2 depicts typical film dosimeters. These dosimeters use a section of photographic type film as a radiation sensor. The film must be processed and read with special optical density sensing instruments to determine the radiation exposure to the individual.

Figure 3.3 depicts a thermoluminescent (TLD) dosimeter. This device uses a radiation sensing element which, when heated, emits light in proportion to the radiation exposure it has received.

Figure 3.4 depicts two types of extremity dosimeters: (a) wrist and (b) finger. Finger dosimeters usually use TLD sensors.

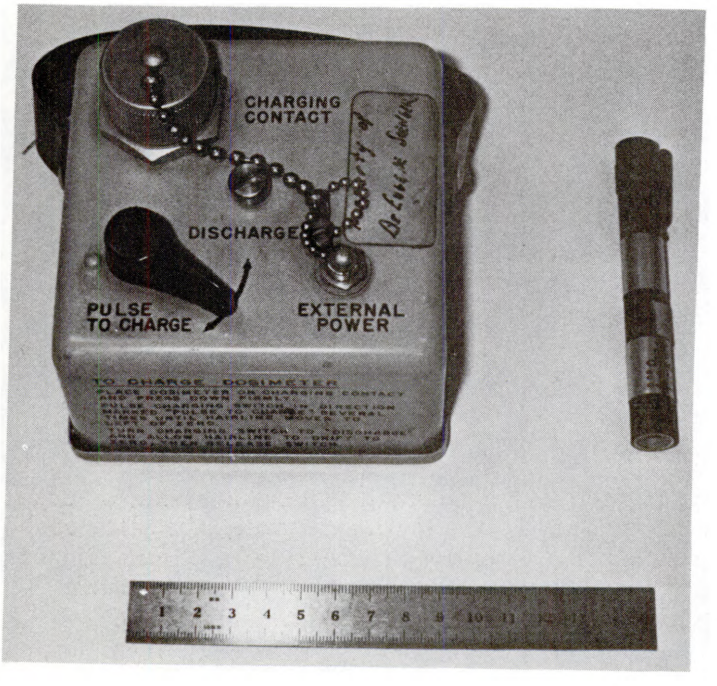


Figure 3.1. Direct reading pocket dosimeter and reader

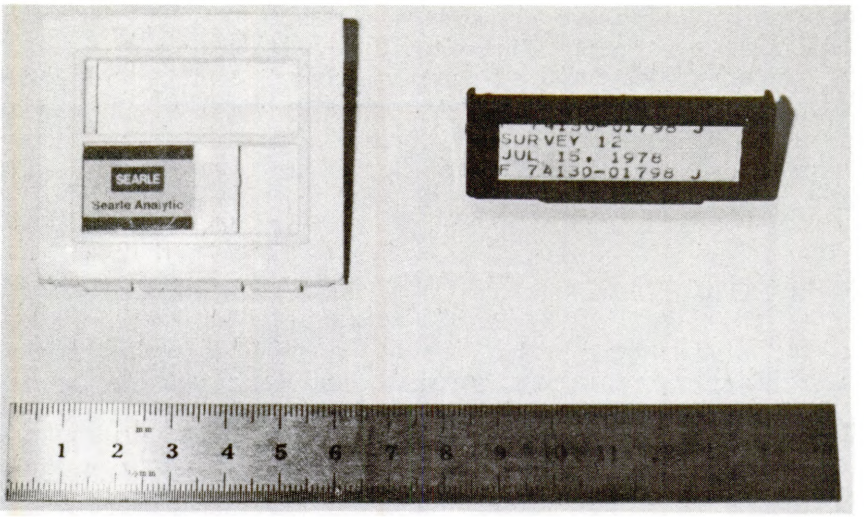


Figure 3.2. Film badge dosimeters

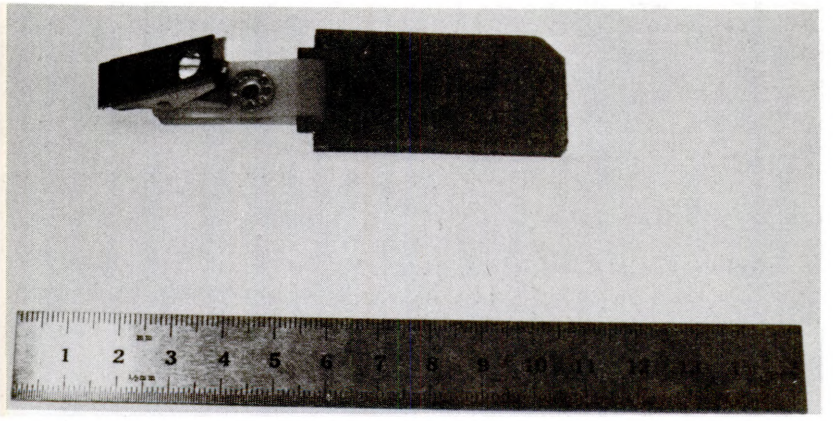


Figure 3.3. Thermoluminescent dosimeter badge

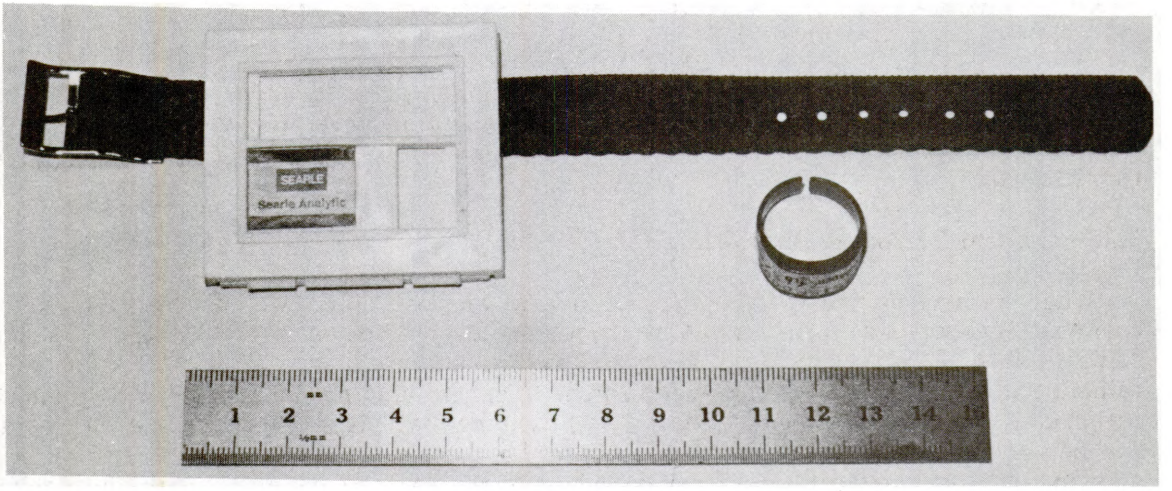


Figure 3.4. Extremity dosimeters: wrist badge; figure ring dosimeter (TLD)

3.3.1 Use of Personnel Dosimeters

One would ideally like to know the radiation exposure to an individual at all locations on the body and be able to accurately detect all radiation types and energies. At this time, that is both economically and technically unfeasible for routine personnel monitoring. Because of this, certain general practices have been arrived at which are compromises based both on cost and personnel protection needs. In clinical nuclear medicine, a single personnel dosimeter is generally worn on the anterior trunk of the body in the chest or waist area. Exposure indicated by this dosimeter is usually assigned as a "whole body" dose for the individual as required by 10 CFR 20.401 (CFR, 1980). It is very important that this personnel dosimeter be worn in such a manner that it is exposed to any radiation sources in a way that represents the degree that the rest of the body is exposed (placement behind a leaded apron, when no protection is provided for the eyes, would not meet this criterion). If an individual is likely to receive a significant dose from radiation sources very close to his body, such as when holding syringes or vials containing radioactive materials, one or more additional personnel dosimeters are usually recommended to monitor the radiation exposure very close to the area of the body that is near to, or in contact with, the radiation sources. These areas of the body are usually fingers, which are monitored with an extremity dosimeter.

One must keep in mind that most personnel dosimeters are calibrated for, and are sensitive to, only certain types of radiations, and only certain energies of those types of radiations. They also have many other sources of error, such as mechanical shock and variations in temperature, humidity, and angle of exposure to radiation sources. Consequently, the proper selection and use of personnel dosimeters must be designated by the facility's health physicist or the radiation protection officer responsible for the nuclear medicine laboratory. It is also important that a personnel dosimeter be worn only during an individual's working time and not during periods such as when the individual is receiving exposure from medical radiation sources used during their own medical diagnosis or treatment.

3.3.2 Who Should Wear Personnel Dosimeters?

Guidelines as to who should wear personnel dosimeters are given in 10 CFR 20.202 (CFR 1980). In general, this includes all workers who are likely to receive more than approximately 320 mrem whole body, 4,690 mrem extremity, or 1,880 mrem skin exposures in any 3-month period (i.e., 25 percent of values in 10 CFR 20.101(a)). Also, any individual under 18 years of age who is likely to receive more than 20 percent of the above values (i.e., 5 percent of values in 10 CFR 20.101(a)) in any 3-month period must wear a personnel dosimeter. In addition, any individual entering a "high radiation area" (an area where one could receive a radiation dose of over 100 mrem to a major portion of the body in 1 hour) must wear a personnel dosimeter.

Individuals such as visitors to a facility, who only occasionally enter "high radiation areas" and do not routinely work with radiation producing sources, are often supplied pocket ionization chamber dosimeters, which can be read out immediately after leaving a high radiation area.

3.3.3 Control Personnel Dosimeters

When measuring an individual's "occupational dose," one would not want to record radiation exposure to the individual from natural sources of radiation (i.e., background radiation), such as cosmic and solar radiations, and radiation from naturally occurring radioactive materials. These include radium, thorium, and uranium, along with their daughter products, which are present in nearly all building materials. To eliminate the reading on the personnel dosimeters from these sources, a common practice is to keep one or more additional personnel dosimeters permanently in the rack or cabinet where the dosimeters assigned to individuals are stored. This should be an area away from any radiation sources used in the facility. These "control dosimeters" are processed when the dosimeters assigned

to individuals are processed, and their readings are subtracted from those on the assigned dosimeters. This tends to remove from the occupational dose both nonoccupational doses and false readings due to radiation-simulating effects to which some dosimeter types are sensitive (such as heat effects on photographic film dosimeters).

3.3.4 Dosimeter Change Intervals

The time interval during which a particular dosimeter is worn is determined by the radiation protection officer. This may be based on many factors, including: (a) variability of exposure conditions and intensity of radiation sources used in particular jobs, (b) dose levels normally encountered by a particular individual in a given time interval, and (c) dose information retention characteristics for the personnel dosimeter being used. Most change intervals range between 1 week and 3 months, with monthly changes being typical.

3.4 RADIATION SURVEYS

Unsealed sources, such as those used in nuclear medicine laboratories, always present a potential hazard in that some radioactive materials may be inadvertently spread to surrounding areas in the laboratory where they can contaminate personnel or equipment. To help control the extent of such contamination and to aid in maintaining safe working procedures, establishment of routine radiation contamination surveys is essential. For similar reasons, it is also important to make routine measurements of the direct radiation dose rates in working areas to ensure that unexpected high dose rates are not encountered by workers due to improper placement of sources or poor working habits. Such surveys are required in 10 CFR 20.201 (CFR, 1980). Appendix I of the NRC Regulatory Guide 10.8 (NRC, 1980) lists the following area survey procedures:

"1. All elution, preparation, and injection areas will be surveyed daily with a low-range, thin-window G-M survey meter and decontaminated if necessary.

2. Laboratory areas where only small quantities of radioactive material are used (less than 200 μCi) will be surveyed monthly.

3. All other laboratory areas will be surveyed weekly.

4. The weekly and monthly survey will consist of:

a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mRem/hr.

b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm/100 cm^2 for the contaminant involved.

5. A permanent record will be kept of all survey results, including negative results. The record will include:

a. Location, date, and type of equipment used.

b. Name of person conducting the survey.

c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

d. Measured exposure rates, keyed to location on drawing (point out rates that require corrective action).

e. Detected contamination levels, keyed to locations on drawing.

f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

6. Area will be cleaned if the contamination level exceeds 200 dpm/100cm^2.

For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey reports will be recorded."

Rates that require corrective action as stated in 5.d are listed in references cited above.

3.5 RADIATION SURVEY INSTRUMENTS

In order to conduct useful radiation surveys, it is necessary to have the appropriate types of survey instruments, properly calibrated for use with the types and energies of radioactive sources present in the laboratory. NRC Regulatory Guide 10.8 recommends certain instrumentation and calibration techniques in Item 9 (Instrumentation) and Item 10 (Calibration of Instruments), as well as in Appendix C (NRC, 1979).

Examples of common survey instruments are given in Figures 3.5 and 3.6.

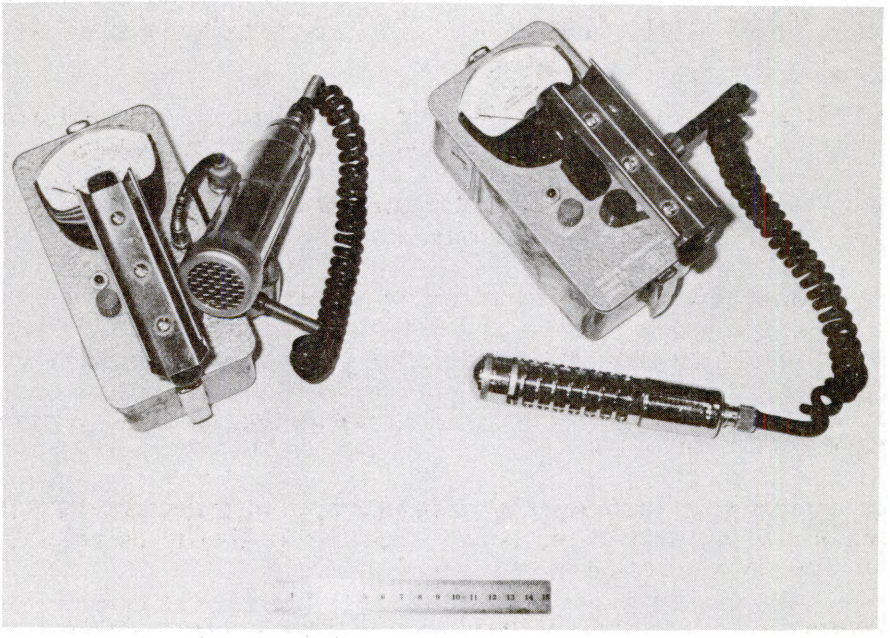
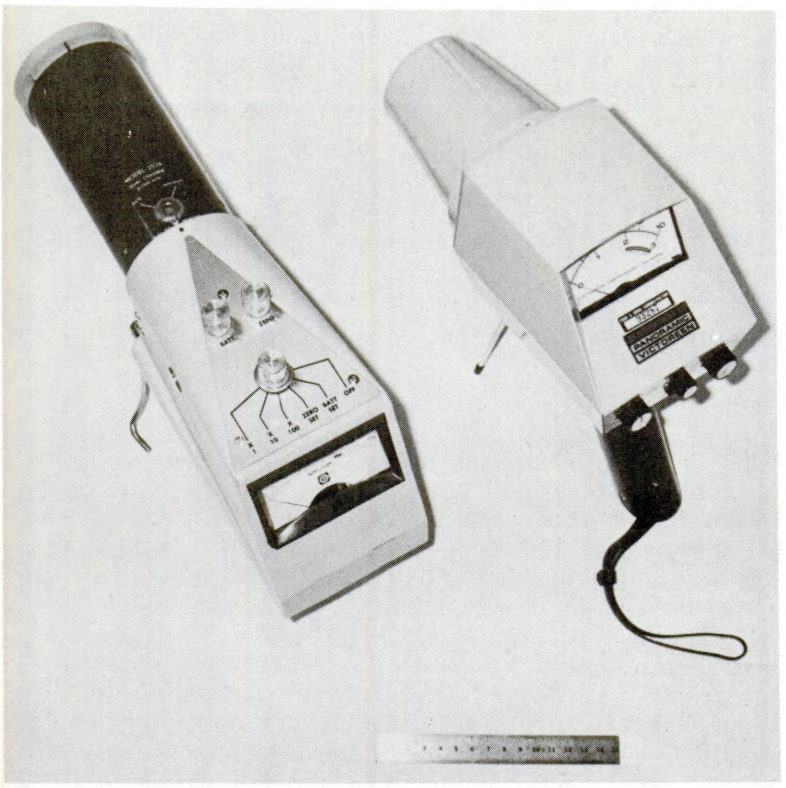


Figure 3.5. G.M. survey meter. (Thin-end window probe; side window probe)

If radionuclides, such as I-125 and H-3, that emit radiations not sufficiently detected by common survey instruments are used (generally for in vitro studies), special survey instruments may be required.

Personnel contamination monitoring is usually accomplished using the same type of survey meter as that used for area contamination surveys. However, special hand and foot monitors that permit rapid monitoring of both sides of the hands and the bottoms of the feet are also available.



3.6. Ionization chamber survey instruments

In most large facilities, removable contamination wipe tests are performed and evaluated by the radiation protection office of that institution. If such tests are to be conducted completely by the nuclear medicine laboratory, special radiation measuring equipment may be required such as gamma radiation well counters. The selection of such equipment will depend on the types of radionuclides used in the laboratory and the requirements for detection sensitivities cited in appendix I of the NRC Regulatory Guide 10.8 (NRC, 1980).

3.6 RECORDKEEPING FOR RADIATION SURVEYS, PERSONNEL DOSIMETRY, AND BIOASSAY

The NRC states in 10 CFR 20.401 that each licensee must maintain records of all personnel exposure readings (from personnel dosimeters) on a Form NRC-5 (CFR, 1979). There are other requirements for keeping records of the results of working area contamination and direct radiation surveys, bioassay, and whole body counting results. Some of these records must be kept indefinitely, while others may be disposed of after a specified period of time. The custodian of such records should consult 10 CFR 20.402 for more detailed information (CFR, 1980).

REFERENCES

Code of Federal Regulations, Title 10-Energy (10 CFR). Office of the Federal Register, (Washington, D.C.: U.S. Government Printing Office), 1980.

U.S. Nuclear Regulatory Commission. NRC Regulatory Guide 10.8: Guide for the Preparation of Applications for Medical Programs. NRC, Washington, D.C. (1980).

4. RECEIVING AND MONITORING RADIOACTIVE SHIPMENTS

Byron M. Branson
Nuclear Medicine Laboratory, DEP, BRH, FDA
Cincinnati, Ohio

When radioactive material is received, it must be checked for contamination, damage, and leakage; then its receipt recorded, followed by proper storage in a shielded area until delivery to its intended use.

4.1 UNPACKING AND WIPE TESTS

Although it is not required that all radioactive materials be monitored upon receipt at the laboratory, it is a wise practice to check all incoming shipments of radioactive materials for external and internal contamination. In this manner, there is control of the spread of radioactive contamination from the point of receipt. Simple wipe tests of the outer package, and the inner package containing the radioactive material, will alert laboratory personnel of potential contamination and allow preventive measures, if required, before experiencing widespread laboratory contamination. The NRC and some State regulations require that recipients of packages containing radioactive material in liquid form or with half-lives of 30 days or greater and a total quantity of more than 100 mCi monitor their external surface for contamination. The packages must be monitored as soon as practicable; within 3 hours if received during normal working hours, or 18 hours if received after normal working hours (CFR, 1980). Specifically exempted from this is "radioactive material in other than liquid form" (including Mo-99m/Tc-99m generators, if they do not exceed Type A quantities) (CFR, 1980). The details of this Code of Federal Regulations, 10 CFR 20.205, should be studied for specific applicability. While most radioactive materials received by the nuclear medicine laboratory will be exempted from this contamination survey, shipments of some radionuclides such as the following must be surveyed:

Cobalt-57	Iron-59	Ytterbium-169
Cobalt-60	Strontium-85	Mercury-203 (liquid)
Selenium-75	Iodine-125	Iodine-131 (> 100 mCi)

For these surveys, a wipe of the package using an absorbant paper over an area equal to 100 cm^2 is counted. If removable radioactive contamination in excess of 0.01 μCi (22,000 dpm) per 100 cm^2 of package surface is found on the external surfaces of the package, the licensee shall immediately notify the final delivering carrier and, the NRC, or the local State radiological health organization (if an Agreement State (see Table 1.1)) (CFR, 1980). In addition, personnel should take every possible precaution to isolate the contamination to prevent its further spread from the package and any areas contaminated by the package.

Radiation exposure control for a nuclear medicine facility begins with the receipt of the package. The U.S. Department of Transportation regulations allow "Radioactive - Yellow II" materials to have a radiation level of 1.0 mrem/hr at 3 ft from the package surface and "Radioactive - Yellow III" packages to have a radiation level of 10 mrem/hr at 3 ft from the package (49 CFR 173 389-394) (CFR, 1980). A laboratory survey meter (or laboratory background monitor) can be used to confirm that those standards were adhered to in the packaging of the radionuclide. If the radiation level is found to exceed the "Radioactive -Yellow II or III" levels, the laboratory will be alerted to take additional protection measures to prevent personnel exposure. It is also suggested that all radionuclides be assayed by gamma spectrometry to assure that the received product is actually as indicated on the label.

4.2 RECORDKEEPING AND INVENTORY

4.2.1 Recordkeeping

Maintaining good records for each radionuclide received is part of a good radionuclide management procedure. Initially, at least two separate records for each radionuclide received should be established, a receiving report and a new entry in the radionuclide logbook. These are discussed in more detail in the following paragraphs.

4.2.1.1 Receiving Reports

A receiving report may be required under a broad license for all radioactive materials received; that is an NRC option. But, whether required or not, a receiving report is your laboratory's record of the condition and other identification for each radionuclide received. Each facility should design its own receiving report. A typically good receiving report would include the information shown in Figure 4.1. This report should be completed at the time of receipt, and the radioactive material placed in storage.

1. Shipment Identification: Supplier
   Radionuclide _____ Lot # _____ Carrier _____

2. Radiation level measured at 1 meter from package ___ mR/h

3. Surface wipe of external package (area 100 cm^2 or greater) End-Window GM _____ C/M Gamma Spectrometer-Scaler _____ C/M NOTE: If the levels are above "reportable" take necessary precautions: Call carrier and NRC and/or State Health Department (circle as appropriate).

4. Open package and wipe internal package or container (surface area 100 cm^2 or as near as possible), measured end-window GM _____ C/M, Gamma Spectrometer-Scaler C/M

   NOTE: If levels above 1/2 "reportable," take contamination control action: call supplier.

5. Gamma Spectrometer Assay
   Radionuclide _____ (Supplier Provided)
   Radionuclide _____ (By Our Assay)
   Contaminants _____ (By Our Assay)

6. Approximate quantity by assay _____ mCi on __/__/____
   Supplier's assay _____ mCi on __/__/____

Report Completed By

Figure 4.1. A typical receiving report.

4.2.1.2 New Entry in Radioactive Materials Logbook

A hardbound logbook should be kept to maintain an inventory/record of all radioactive material received. In this logbook, each new shipment of radioactive material is recorded on a separate, new page. The initial entry should duplicate the basic information from the receiving report, Figure 4.1; items 1, 5, and 6. The first entry should indicate the storage location specifically to facilitate finding the radionuclide with a minimum of search. The

remainder of the page should be used to enter data about the distribution and use of the material. See section 4.4 for a discussion on distribution to users. (Suggestion: Have a large rubber stamp made with items 1, 5, 6 and storage location listed with fill-in space provided. This can be used in the logbook and for the inventory records, section 4.2.2.)

4.2.2 Inventory

It is important to maintain an inventory record of all radionuclides received. This record should list the name, quantity, purity, and location of each radioactive material and all dilutions of that material.

4.2.2.1 Long-Lived Radionuclides (over 5-day half-life)

Each laboratory must determine the best way to maintain such an inventory record. One good method is a 4" x 5" index card file, with radioisotopes filed in alphabetical order, one card for each radionuclide container. If the radionuclide is subdivided, then that should be noted in the logbook, and on the index card. Then a new index card is created for the new containers of the subdivided radionuclide.

Cards for "retired" or "disposed" radionuclides are transferred to a second card file when the radionuclide is completely used, or it has decayed to a point where the radionuclide is of no further use.

A final entry on the card should indicate the details of disposal as given in Chapter 9 before transferring to the second file. All cards should be kept, as they may be necessary to satisfy NRC or State regulatory inspectors desiring proof of accountability.

4.2.2.2 Short-Lived Radionuclides (under 5-day half-life)

A simple method for short-lived radionuclides is a "Short-Lived Radionuclide Logbook," about 8-1/2" x 11" in size, in which all the records are kept for a specific radionuclide. Since the short half-life limits its useful existence, all the dilutions, use, and disposal can be recorded in the logbook. Again, all records should be kept as proof of accountability.

4.3 STORAGE

Received radionuclides should be stored in a shielded area as soon as the contamination and gamma spectrometry survey and record-keeping procedures have been completed. The degree of security provided for the stored radionuclides will be dependent on the location of the storage and the inventory of radionuclides stored. Where the storage area is easily accessible or in the traffic pattern, a secured storage area is necessary. It is prudent to shield the laboratory work area adjacent to the storage area, to maintain a radiation exposure level of less than 2 mR/hr even though the area does not require placarding as a "radiation area" (CFR, 1980). Most radionuclides used in nuclear medicine laboratories, including molybdenum-technetium generators, can be easily shielded with lead.

Even where the entire storage cabinet is shielded, containers should be individually shielded to protect workers when opening the cabinet. Also, when multiple sources are put together, they may exceed a safe radiation level, thus requiring a thicker shield. The contents should be clearly marked on the shield exterior in lettering large enough to read from a few feet away. Shelves should be divided into sections, each identified on the front edge to aid the identification and the exact storage location entered in the inventory record card.

While it may not be required in all States, it is wise to keep the radionuclide storage in a locked area with limited traffic and under the control of individuals who are specifically intended as being responsible for their receipt, inventory, storage, transportation, and usage.

Section 2.2.2 contains additional information about storage area.

4.4 DISTRIBUTION TO USERS

For distribution to users, a basic consideration is the qualification of the intended users. Most institutions will require users to submit a protocol giving pertinent information about themselves, their proposed project/use, assistants, and laboratory facilities. Users must have a knowledge of radioisotope procedure and safety precautions. They are responsible for assuring adequate training to all of their personnel and are responsible for all records required by the Radiation Protection Officer and Radiation Safety Committee (Kincaid, 1976; USDHEW, 1972).

When a radionuclide is consigned to be used outside the nuclear medicine laboratory, that should be recorded in the logbook and on the inventory card. The information included should cover the following (which might be placed on a rubber stamp to be used whenever such distribution occurs):

Name_____	Radionuclide_____
Department_____	Amount at Assay_____
Phone No._____	Date of Assay_____
Date_____	Dispensed by_____

The distribution of radionuclides outside the nuclear medicine laboratory must be under the authority of the Radiation Safety Committee, and the Radiation Protection Officer, who will assume primary responsibility once the nuclide has been consigned by the laboratory.

REFERENCES

Code of Federal Regulations, Title 10-Energy (10 CFR) Office of the Federal Register (Washington, D.C.: U.S. Government Printing Office), 1980.

Code of Federal Regulations, Title 49-Transportation (49 CFR) Office of the Federal Register (Washington, D.C.: U.S. Government Printing Office), 1980.

Kincaid, C.B. Radiation Safety Handbook for Ionizing and Nonionizing Radiation. DHEW Publication (FDA) 77-8007, (1976).

U.S. Department of Health, Education, and Welfare (USDHEW) DHEW Publ. (NIH) 73-18, (1972).

5. RADIATION SAFETY DURING RADIOPHARMACEUTICAL PREPARATION

Philip J. Robbins and Vincent J. Sodd
Nuclear Medicine Laboratory, DEP, BRH, FDA
Cincinnati, Ohio

5.1 FACTORS GOVERNING RADIATION EXPOSURE

As is the case when handling any radioactive material, the external exposure encountered when preparing radiopharmaceuticals is determined by the exposure time, the distance from the source, and the shielding. It is important that all three of these factors be given consideration when methods of preparation are being developed.

5.1.1 Time

Decreasing the exposure time decreases the radiation exposure in direct proportion. Hence, when establishing procedures to be done repeatedly in the laboratory, it is important to preplan every step to include as many time-saving techniques as possible. Occasionally, a fast procedure may be preferred to one that is more efficient, in order to reduce exposure time. With short half-lived radionuclides, which are usually used, the faster procedure would allow less nuclear decay and, hence, might actually result in an overall greater yield.

When doing a nonroutine procedure that requires the introduction of a high level of radioactivity, it is recommended that trial runs be conducted to test the adequacy of the procedure and equipment before introducing the activity.

It may be necessary occasionally to work in areas of high dose rates in order to complete a task. This can be accomplished in a safe manner by a careful time division of the sequential procedure. Alternatively, several people can perform individual segments of the procedure so that individual exposures are kept to a minimum and well within permissible limits.

5.1.2 Distance

Increasing the distance between the individual and the source is often the simplest and most effective method to reduce radiation exposure from γ-ray-emitting radionuclides. In radiopharmaceutical preparation, where the sources are small compared to the distance, the radiation field can be assumed to vary inversely with the square of the distance. Therefore, doubling the working distance reduces the exposure by a factor of four. For this reason, tongs or other remote-handling tools should always be used when working with radiopharmaceuticals emitting significant levels of radiation. Radioactive material should never be picked up directly with the fingers. When preplanning procedures, it is important to integrate the use of clamps and other holding devices instead of using a hand merely to steady the source while manipulating it with the other hand. Furthermore, perform segments of a procedure prior to the introduction of the radioactive source as far from the source as is practicable.

5.1.3 Shielding

Shielding the source of radiation is necessary when the maximum distance and minimum time do not result in a sufficiently low exposure to laboratory personnel. The type of shield required depends upon the energy and the nature of the radiation. When dealing with beta radiation, it is best to use a shield made of low atomic number material because high atomic

number materials such as lead can cause the emission of bremsstrahlung radiation that is highly penetrating. For gamma radiation, attenuation is exponential in nature according to the equation $I = I_o e^{-\mu x}$ where x is the distance traveled by the photon in the absorber and μ is the linear attenuation coefficient. Values for μ can be found in most handbooks and tables of physical data. Also readily available is the mass attenuation coefficient, μ_m which is independent of the physical state of the absorber and is defined as $\mu_m = \mu/\rho$, where ρ is the density of the absorber. Thus, the attenuation equation becomes $I = I_o e^{-\mu_m (\rho x)}$ where ρx is the density thickness of the absorber and has units of g/cm^2. The density of lead is 11.35 g/cm^3; its density thickness is 29.2 mg/cm^2 per each 0.001 inch of thickness. Another way of expressing the shielding capability of a material is by its half-value layer (HVL) for a particular energy photon. The HVL is the thickness of a specified substance which, when introduced into the path of a given beam of photon radiation, reduces the exposure rate by one-half. The HVL can be calculated using the equation, $HVL = 0.693/\mu_m \rho$. Most package inserts for radiopharmaceuticals list the HVL for the primary photon radiations as well as other information that will aid in choosing a proper shield. For example, the following Table was published in the E.R. Squibb & Sons, Inc. product literature for a Tc-99m radiopharmaceutical kit dated May 1981:

Table 5.1. Tc-99m Radiation Attenuation by Lead Shielding

Shield thickness	Attenuation factor
0.2	0.5
0.8	10^{-1}
1.6	10^{-2}
2.5	10^{-3}
3.3	10^{-4}

(As published in Package Insert for Tc-99m Medronate Kit, E.R. Squibb, Inc., 1981)

For example, according to this Table, the HVL for the 140 keV photon of Tc-99m is 0.2 mm. Also, the use of a 2.5 mm thickness of Pb will attenuate the radiation emitted by a factor of about 1,000.

5.1.3.1 Bench Top Shielding

Most laboratory procedures using a significant quantity of a gamma-emitting source can be performed safely behind a shield constructed of lead bricks. Lead bricks with interlocking surfaces are preferred over the straight-edged type because they result in more sturdily constructed walls and prevent leakage of radiation that occurs with the straight-edged construction. This leakage can occur frequently through the single layer of bricks normally required for low-energy gamma emitters such as are used in nuclear medicine.

In erecting and locating a shield, the following points should be considered:

1. The shield should be large enough and positioned to shield workers wherever they might have to be located in the room.

2. The bottom of the work area should be shielded if the working surface itself does not afford sufficient protection to the lower part of the body.

3. The working surface must be able to support the weight of the shielding.

4. Personnel located in adjacent rooms must not be exposed to radiation from unshielded sides of the work area.

5. If required, a mirror should be positioned to avoid direct exposure of the eyes to the source.

6. Radiation can be scattered "around shields." A survey meter should be used to determine that the shield is effectively placed.

Table-top shields have been designed specifically for low-energy gamma radiation such as that emitted from Tc-99m generators. The horizontal support of these shields serves as the working surface and is made of approximately 5/8-inch thick lead plates; the transparent vertical portion made of either lead glass or a plastic cell filled with a nearly saturated solution of lead perchlorate serves primarily as a face shield (**Barnett, 1970**). The high visibility afforded by the transparency of the lead glass or perchlorate solution facilitates rapid and accurate procedures. Shields of this type are available commercially.

5.1.3.2 Syringe and Vial Shields

Calculations (**Henson, 1972**) have indicated that careless handling of short-lived radionuclides, such as Tc-99m, In-113m, and Ga-68, may cause individuals to exceed the maximum permissible dose to the skin. The maximum permissible dose to the skin of the whole body is 7.5 rem/quarter (**CFR, 1980**). It is quite possible to reach or exceed this dose if multi-mCi quantities of radioactivity in thin-walled plastic syringes are handled directly. A great percentage of the possible skin dose to the hands of those performing nuclear medicine procedures can be eliminated by the use of syringe and vial shields.

Syringe shields have usually been made of lead or other high atomic number material with a window of lead glass. Some recent models have been available made almost entirely of lead glass. These latter types eliminate the added time, and hence exposure, required to align the volumetric markings on the syringe with the glass window.

It has been reported (**Branson, 1976**) that exposure to the user's hands while preparing radiopharmaceuticals can be reduced by as much as 50 percent by the use of syringe shields and that the maximum reduction to the person administering the activity to the patient can be as high as 80 percent.

Dispensing vials containing mCi quantities of radioactivity should be stored and used in shields designed for this purpose. This is especially necessary when handling eluates from Mo-99 - Tc-99m generators, where the total activity normally exceeds hundreds of mCi's. As with the syringe shields, both lead and lead glass protective containers are available. When withdrawing liquid from a shielded vial, it is helpful to observe the fluid level in relation to the needle tip, so transparent shields are preferred if equal shielding can be maintained.

Because the transfer of an aliquot from a vial to a syringe requires that the vial be held with the rubber septum downward, it is advisable to construct a rack to hold the shielded vial in this position. This eliminates exposure to the hand one would normally use to hold the vial and also reduces fatigue, as vial shields can be very heavy. Of course, one must become adept in using remote devices, since the time of exposure can be significantly decreased with practice.

Some Mo-99 - Tc-99m generators are available with custom-fitted vial shields that eliminate both unnecessary handling and leakage of radiation through ill-fitted surfaces.

5.2 GENERAL LABORATORY RULES

The following basic rules should be observed when working with radioactive materials in the nuclear medicine laboratory:

1. Unsealed sources should be handled in a hood, except when being administered to the patient.

2. Lab coats and rubber gloves should be worn.

3. Radioactive materials should be kept in closed containers.

4. All containers of radioactive material should be labeled with nuclide name, quantity of activity, and date of assay.

5. All working surfaces and transport devices (such as trays and carts) should be covered with absorbent paper coated on the reverse side with a nonpermeable plastic.

6. All spills, including those resulting from incontinence, must be cleaned up immediately.

7. Pipettes should be used with mechanical devices and never orally.

8. Eating, drinking, smoking, and loitering are prohibited in areas where radioactive material is handled or stored.

9. Procedures not requiring radioactive materials should not be performed in an area where radioactive materials are used.

5.3 Mo-99, Tc-99m GENERATORS

By far, the most commonly used radionuclide in nuclear medicine is Tc-99m. Practically all Tc-99m used in medicine is obtained from commercially available Mo-99 - Tc-99m generators. In an active nuclear medicine laboratory, where Tc-99m radiopharmaceuticals are prepared daily, at least one and perhaps two or more generators of this type are purchased each week. When eluted some of these generators can yield more than 1 curie of Tc-99m. Hence, they are the largest potential source of external radiation exposure to nuclear medicine personnel other than the 100-mCi quantities of I-131 used for therapy. These generators are manufactured with shielding adequate to protect the user from the Mo-99 and ingrown Tc-99m located on the exchange column, when stored in the manufacturer-supplied additional permanent shield. However, it is good practice to isolate these generators in a separate shielded area or room to minimize personnel exposure. Suggestions on suitable locations for these generators are given in Chapter 2.

The user should be in the vicinity of the generator only when it is being eluted. Once the generator is eluted, usually directly into a dispensing vial, it is up to the user to provide sufficient shielding for the eluate. Some manufacturers supply vial shields that are directly compatible with their generators so that the entire elution process can be accomplished with the apparatus completely enclosed in shielding.

5.4 EXHAUST AND LAMINAR-FLOW HOODS

Three types of hoods are used in nuclear medicine laboratories: conventional exhaust hoods, laminar-flow hoods, and laminar-flow exhaust hoods. An exhaust hood, normally used in chemical laboratories, is an enclosure from which the toxic and/or radioactive fumes of a chemical reaction are removed by means of an exhaust fan. An exhaust hood should be equipped with a filter in the exhaust line if radioactive material is expected in the exhaust. These hoods may also be equipped with lead shielding and remote handling devices if necessitated by the level of radioactivity and the time spent on the procedure. A properly placed mirror makes it possible to follow the operations without direct exposure to the head. Exhaust hoods with remotely-controlled manipulators and adequate construction to support the heavy weight of lead shielding are available commercially.

While the exhaust hood is effective in protecting personnel from toxic and/or radioactive fumes, it is not designed to provide a sterile environment for pharmaceutical preparation, as are the laminar-flow hoods. In the laminar-flow hood (or clean-air bench), illustrated in Figure 5.1, a sterile environment is maintained by passing the circulating air through a high efficiency particulate air (HEPA) filter. The filtered air is directed over the work area in a laminar flow and pushed out of the hood toward the operator. This prevents airborne contaminants from entering the work area from the operator's area but volatile gases and particles can be blown out at the worker. This type of hood is used in preparation of sterile, nonradioactive components of radiopharmaceutical kits, but should never be used in handling radioactive or chemically toxic materials.

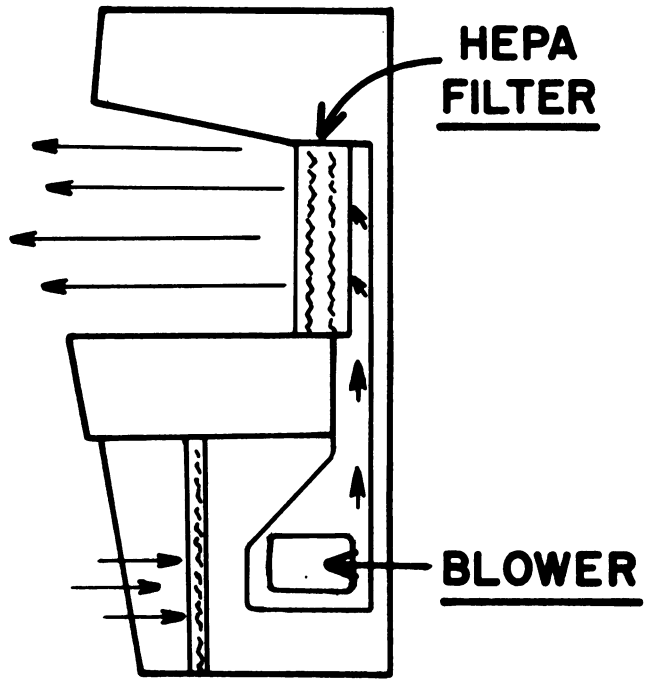


Figure 5.1. Laminar-flow hood

In nuclear medicine, the worker is interested in protecting an open container of radioactive material, usually a solution, from bacterial contamination while also protecting personnel from contamination by radioactivity from the material. To accomplish this, a laminar-flow exhaust hood is required. This containment-type cabinet not only provides a work space that is protected from the ambient working environment, it also provides an ambient working environment that is protected from the experiment done in the work space. A diagram of this type of hood showing the design, HEPA filtering system, and air-flow patterns is given in Figure 5.2. This type of hood is sold primarily as a biological hazard hood. With some structural modification, the work area can handle the heavy load of a lead brick shield that may be required for some procedures.

Each of the three hoods described has its particular application. Exhaust hoods should be used for storage and when handling volatile materials such as I-131 solutions from which therapy and thyroid uptake doses are withdrawn. These solutions typically contain approximately 25 mCi/ml of I-131 as sodium iodide, but it is possible for other oxidation states of iodine also to be present. It is the volatile HI or I_2 form that can escape when the flask is open. For the same reason, high-specific-activity I-123 solutions that are going to be used in radiopharmaceutical preparation also should be handled in the hood. Technetium generators do not need to be placed in a hood, since none of the oxidation states of technetium is volatile at room temperature.

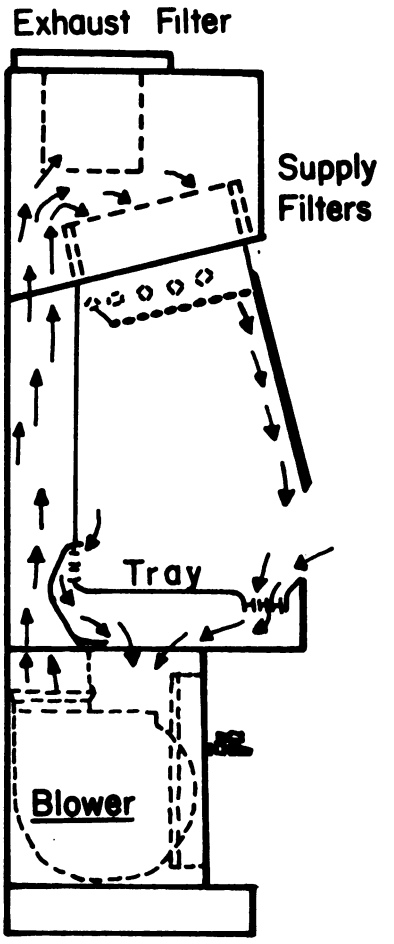


Figure 5.2. Laminar-flow exhaust hood

A laminar-flow hood (clean-air bench) is used for preparation of the sterile, non-radioactive kit components. With the large scale availability of commercial kits, this type of hood is rarely needed except at institutions where new radiopharmaceutical kits are being developed and evaluated clinically. The preparation and bottling of reagents for Tc-99m kits are customarily done in a clean-air bench.

A laminar-flow exhaust hood is required to maintain sterility and protect the operator from inhalation of open sources of radioactivity used in radiopharmaceutical preparation. Preparation of all radiopharmaceuticals that involve open beakers or containers should be done in this type of hood.

5.5 REMOTE HANDLING DEVICES

The obvious advantage of any remote handling device in nuclear medicine is the reduction in radiation exposure because of the distance from the radioactive source. There are many instances in radiation therapy where large quantities of I-131 are used and in diagnostic nuclear medicine where high activities of short half-life radiopharmaceuticals are handled. A typical instance where the use of a remote handling device is advisable is in transporting the primary eluate from a multi-hundred mCi Mo-99 - Tc-99m generator; especially when the vial is removed from its shield for assay. A sponge forceps is useful for picking up radiopharmaceutical vials by the top. Remote handling devices may be used alone or in conjunction with protective shielding. Grip tongs and other remote controlled devices for handling radioactive sources are available commercially.

5.6 HOT CELLS

To protect the body from penetrating radiation, gamma emitters are frequently handled from behind a sheet of lead glass or a wall of lead bricks; in the latter case, a carefully placed mirror makes it possible to follow the operation without direct exposure to the head. Exposure of the hands and arms, however, cannot be avoided when using the simple lead-wall shield. In instances where exposure to the extremities can be significant, it is essential to use gripping tools or remote handling instruments and to conduct the operations as quickly as possible.

When the activity is very high, it may be necessary to perform the handling operation in a shielded hot cell by means of a master-slave device or remote handling tools. A typical hot cell constructed of 2-inch-thick interlocking lead bricks with a lead glass window and remote handling tools is shown in Figure 5.3. The floor of such a unit should also be constructed of interlocking lead bricks to reduce penetrating radiation to the gonadal area of the operator.

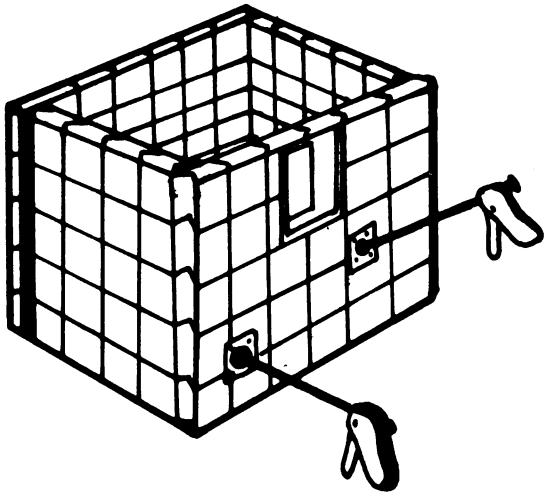


Figure 5.3. Hot cell with lead-glass window and remote handling tools

Hot cells are often placed in fume hoods when the operation involves large quantities of radionuclides and is likely to create volatile materials that might be inhaled by the operator. Interlocking lead bricks, lead glass windows, and the other accessories for building a custom hot cell are commercially available.

REFERENCES

Barnett, H.D. and C.C. Harris. A Means of Reducing Radiation Exposure from Technetium Generator Operations. J Nucl Med 11, 180 (1970).

Branson, B.M., V.J. Sodd, H. Nishiyama, and C.C. Williams. Use of Syringe Shields in Clinical Practice. J Clin Nucl Med 1, 56 (1976).

Code of Federal Regulations, Title 10-Energy (10 CFR) Office of the Federal Register (Washington, D.C.:U.S. Government Printing Office), 1980.

Henson, P.W. A Note on Some Aspects of Skin Contamination by Certain Radionuclides in Common Use. Brit J Radiol 45, 938 (1972).

6. ACCURATE ASSAY OF ADMINISTERED ACTIVITY

Richard J. Van Tuinen
Nuclear Medicine Laboratory, DEP, BRH, FDA
Cincinnati, Ohio
and
James G. Kereiakes
The Eugene L. Saenger Radioisotope Laboratory
Department of Radiology
University of Cincinnati

Radionuclide calibrators are used in most nuclear medicine departments to assay the activity of radiopharmaceuticals to be administered to patients. In some cases, the radiopharmaceutical is delivered precalibrated by the commercial supplier, or a radiopharmacy. In other cases, the radiopharmaceutical may be prepared on site, usually with the eluate from a radionuclide generator. In either of these cases, the radiopharmaceutical activity must be assayed to an accuracy of ± 10 percent prior to administering it to the patient (NRC, 1980; USPC, 1980). The responsibility for the accuracy of the activity and the concomitant estimate of the dose rests with the persons administering the radiopharmaceutical. Hence, it is essential that accurate measurements of radioactivity be provided by the radionuclide calibrator in use in every nuclear medicine department.

6.1 PRINCIPLES OF CALIBRATOR OPERATION

Well ionization chamber type calibrators are preferred for routine use in most clinical nuclear medicine departments because they accommodate a wide range of activity measurements and exhibit reasonable stability of performance from day to day. Additionally, well ionization chamber calibrators are easy to use and their readings are easy to interpret. The basic design of a calibrator includes an ionization chamber coupled to appropriate circuitry to convert the ionization current to a display in units of activity. A block diagram of a radionuclide calibrator is shown in Figure 6.1. The ionization chamber consists essentially of a sealed, gas-filled (usually argon), double-walled cylinder. When a radioactive source is lowered into the well, radiation emitted from the source ionizes the gas within the chamber and produces a current. The current is sensed by an electrometer which develops an output voltage proportional to the input current. The output voltage is then fed to the readout device after adjustments for range and nuclide selection are made. The adjustments for a specific radionuclide are accomplished with the appropriate plug-in module calibrated for that radionuclide or by means of a continuous, variable potentiometer existing as part of the controls for a calibrator. The signal output is registered either as an analog display on a milliammeter with a scale marked in units of microcuries or millicuries, or converted to a digital readout in similar units.

6.2 CALIBRATOR USE CONSIDERATIONS

Most ionization chambers are very sensitive to thermal and mechanical shocks. Hence, care must be taken so that the calibrator is not moved or jarred after it has been installed. Also, it should not be turned off or subjected to rapid fluctuations in temperature. When these situations do occur, after conditions have stabilized, tests should be performed to ensure that the calibrator is operating properly. As with any nuclear medicine equipment, the calibrator should be kept in a clean, dry, low-background radiation area, and used in the environment in which it was calibrated to assure the most reliable performance. Accordingly, shielding used to protect personnel or equipment from radiation should not be

moved because this may produce a change in the amount of scattered radiation and hence, change the calibration accuracy as well as the background. In general, background corrections are important when measurements are in the microcurie range.

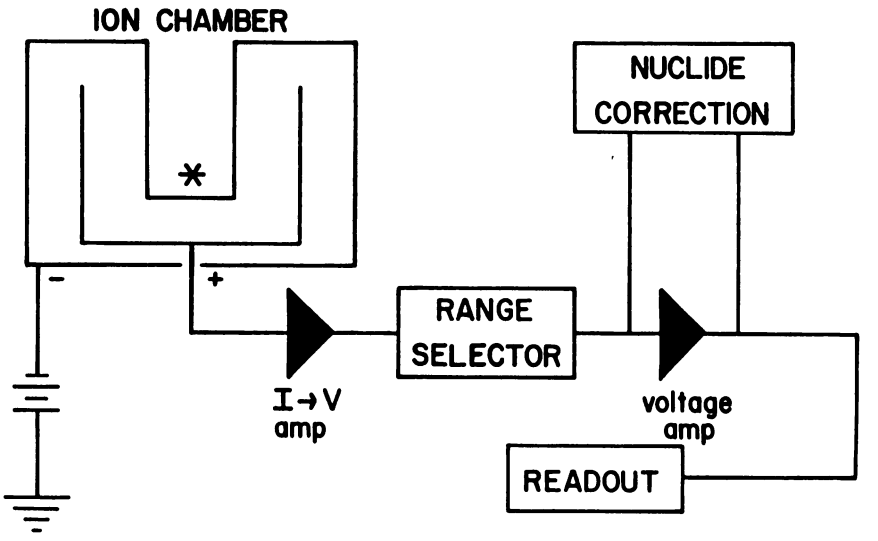


Figure 6.1. Block diagram of a radionuclide calibrator.

6.3 INSTRUMENT CALIBRATION

Studies of well ionization type calibrators indicate the need for accurate calibrations (Hare, 1974; Genna, 1972; Payne, 1974). Calibrators described in these studies frequently were inaccurate by 10 percent, and occasionally by as much as 25 percent. Many professional groups agree that yearly calibration, with recalibration after each servicing of the instrument, is sufficient to ensure the accuracy of a calibrator if daily quality control testing is also performed (USDHEW, 1977; ANSI, 1978).

It is important that the calibration be performed with clinically applicable radionuclides and activities. This concern has been stated in the American National Standard Calibration and Usage of "Dose Calibrator" Ionization Chambers for Assay of Radionuclides (ANSI, 1978). In Section 4.2 of the report is the following:

> "Initial Calibrations: Instruments shall be calibrated with identified radionuclide sources of known activity and established purity ... calibrations should be performed with standard sources of each radionuclide of interest, if at all possible."

Calibration accuracy may be verified by using radionuclide standards spanning a wide energy range, i.e., Co-57, Cs-137, and Co-60 traceable to National Bureau of Standards (NBS) calibration, and determining the present activity of each source versus the calibration setting. Sources suitable for calibration are shown in Table 6.1; some of these may be obtained from the NBS, or from a number of suppliers.

Table 6.1. Reference sources

Source	Activity	Principal energies	Simulated radionuclides
Co-57	1-2 mCi	122, 136 keV	Tc-99m
Cs-137	100-200 μCi	662 keV	Mo-99
Ba-133	50-100 μCi	356, 302, 80 keV	I-131
Co-60	50 μCi	1.17, 1.33 MeV	-
Ra-226	20-40 μCi	0.55[a], 1.65[a] MeV	-

[a] average

In addition, standard samples of I-131 and Tc-99m may be prepared using the method described by Hare, et al. (1974). Determination of calibration accuracy is affected by geometrical factors, i.e., position of the source in the chamber, as well as the size of the container.

6.4 SOURCES OF ASSAY ERROR

The position, size, shape, and material of the radioactive sample container may all influence the measured activity. To determine these influences and to obtain correction factors, some tests, that are described below, must be performed. The performance of calibrators may also be somewhat dependent upon the amount of radioactivity being assayed. For example, readings are frequently inaccurate in the high millicurie range, and a correction curve should be obtained to correctly assay high activity samples (e.g., eluate from a generator). Protocols for obtaining these factors, as well as other recommended tests are provided.

6.4.1 Geometry Effects

There may be significant variation in measured activity as a function of counting geometry (height, width, wall thickness, and composition of sample container) and sample volume, depending on the volume and size of the chamber used in the radionuclide calibrator. Measurement errors will be minimized if a standard container and volume are used for all measurements. This is particularly true for radionuclides that decay with low-energy emissions, such as Iodine-125 and Xenon-133.

The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than ± 2 percent (even though correction factors may be provided by the manufacturer, the accuracy of these should be checked).

6.4.1.1 Procedures for Measuring Geometry Effects

1. Use a 30 cc vial containing 2 mCi of Cobalt-57, or other appropriate radionuclide in a volume of 1 ml.

2. Assay the vial at the appropriate instrument setting and subtract background level to obtain net activity.

3. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 2.

4. Select one volume as reference standard and calculate the ratio of measured activities (A_m) for each volume to the reference volume activity. These ratios represent the volume correction factors (CF).

Example: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4-, 8-, and 10-ml volumes, respectively, and 10 ml is the reference volume selected, then the correction factor for a 4-ml volume is:

$$CF = \frac{2.00}{2.04} = 0.98$$

5. Plot the correction factors against the volumes on linear graph paper.

6. Use the graph to select the proper volume correction factors for routine assay of that radionuclide. The true activity (A_t) of a sample is calculated as follows:

$$A_t = A_m \cdot CF$$

Note, the CF used is for the same volume and geometrical configuration as the sample measured.

Similarly, the same activity of Cobalt-57 in a syringe may be compared with that in 10 ml in a 30-cc vial and a correction factor calculated.

It should be noted that differences of 200 percent in calibrator readings between glass and plastic syringes have been observed for lower energy radionuclides such as I-125. Hence, adequate correction factors must be established for low-energy photon emitters.

As an alternative to determining syringe calibration factors, the stock vial may be assayed before and after filling the syringe. If the stock vial is similar to the reference calibration vial, the activity in the syringe is then the difference in the two readings (with a volume correction, if significant).

6.4.2 Linearity of Assay

Quarterly testing should be performed to check the calibrator for linearity dependence as a function of activity (NRC, 1979). For example, readings are frequently inaccurate in the high millicurie range and a correction curve should be obtained to correctly assay high activity samples, e.g., Mo-99 - Tc-99m generator eluate. Linearity of response over a range of activities may be verified by successive calibrator readings of a high activity, short-lived source such as Tc-99m.

6.4.2.1 Procedure for Measuring Linearity

1. Prepare a vial containing at least several hundred mCi of Tc-99m (with not more than 10 μCi of Mo-99 present).

2. Adjust the calibrator selector dial for Tc-99m.

3. Adjust the calibrator background control until a reading of zero is obtained (if this is impossible, record the background reading).

4. Assay the vial in the calibrator, recording the time and net reading.

5. Repeat step 4 at convenient time intervals such as 2, 4, 6, 24, 30, and 48 hours, or until the Tc-99m source decays to approximately 100 μCi.

6. Plot the measured net activity vs. time on semilog paper (see Figure 6.2).

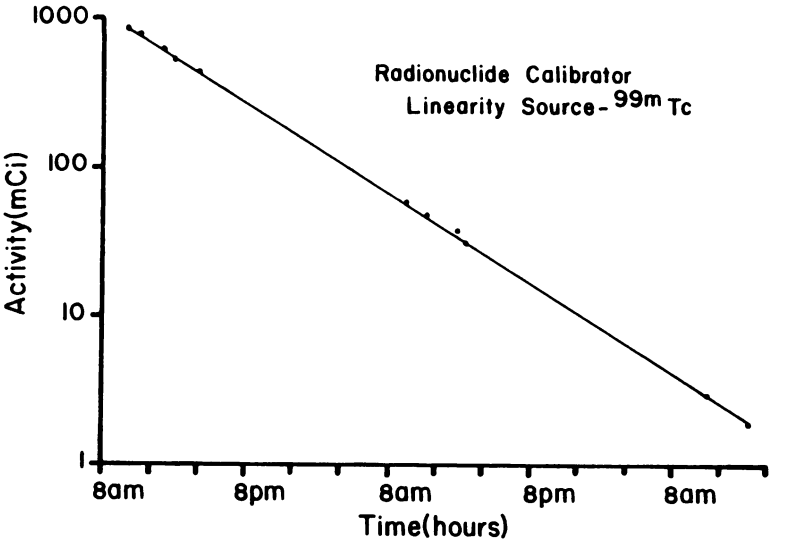


Figure 6.2. Radionuclide calibrator linearity

7. Using the activity measured at 30 hours, calculate the activity (using physical decay correction) that should have been present at the time of the first measurement.

8. Plot the activity determined in step 7 and draw a straight line between this point and the point at 30 hours.

9. The measured activities should be within ± 5 percent of the decay predicted curve if the calibrator is performing in an acceptable linear manner.

6.4.3 Self Absorption and Container Attenuation Variations

Radioisotopes of predominantly low energies (< 50 keV), such as I-125 (27 keV x rays) and P-32 (1.7 MeV β max plus low-energy bremsstrahlung), should be individually calibrated in each encountered geometry. For example, a calibration setting should be known for these radionuclides, both when in a specific type of syringe and when in a particular size vial. To illustrate this fact, the readings shown in Table 6.2 were obtained for an I-125 source (nominal 110 μCi) in a thin glass ampule at the suggested calibration setting.

Table 6.2. Calibrator measurement of I-125 activity (110 μCi ± 5%)

Source configuration	Calibrator reading
Ampule alone	208 μCi
Ampule in empty 30 ml bottle	71 μCi
Ampule in 30 ml bottle filled with saline	58 μCi

The method described by Dubuque et al. (1976) may be used to obtain a calibration setting for radionuclides not included in the chart supplied by the manufacturer.

Measurement of radionuclides emitting both intermediate- and low-energy photons, for example I-123 and Cs-129, is complicated by the disproportionate ionization produced at various photon energies. The counting problem caused by the geometry dependence for low-energy photons may be circumvented by attenuation of these photons. A filter of appropriate thickness, constructed to fit into the calibrator chamber, will sufficiently attenuate the low-energy photons. This allows the radionuclide of interest to be assayed by measuring the intermediate-energy photon in any container with no further correction for geometry.

A copper tube (12" long, 2-1/4" O.D., 0.055" wall) closed on one end with a copper disc soldered in place may be used. With this filter inserted into the calibrator well, sufficient attenuation of low-energy photons occurs. Table 6.3 illustrates the measurement of 0.1 ml of Cs-129 in a 1 ml tuberculin syringe with and without the filter; and also with the syringe inserted into an empty 30-ml vial. The difference between activity readings of the plastic syringe and glass vial was less than 2 percent, whereas, without the copper filter, the difference was 30 percent. Other mixed-energy radionuclides whose activity can be measured accurately with a filter of this type include Ga-67, I-131, and Se-75.

Table 6.3. Calibrator measurement of Cs-129 (93 μCi)

Source configuration	Calibrator readings (microcuries)	
	With Cu Filter CS[a] = 83	Without Cu Filter CS[a] = 346
Syringe	93.0	133.5
Syringe in vial	91.7	93.0

[a]Calibrator setting

6.5 CALIBRATOR QUALITY CONTROL AND MAINTENANCE

Routine testing of the calibrator, as part of an ongoing daily quality control program is required of nuclear medicine facilities (JCAH, 1980). This testing ensures that the calibrator is operating in the same manner day by day, and that the calibration accuracy is still valid. The ANSI report on Calibration and Usage of "Dose Calibrator" Ionization Chambers for Assay of Radionuclides states in Section 4.5.1:

> "Reference Source Checks: Calibration checks using at least one long-lived reference source (e.g., Cs-137) shall be performed and logged on each workshift during which the instrument is used" (ANSI, 1978).

Long-lived standards in the energy range and activity of interest are preferred for this type of testing. Acceptable standards include Cs-137 (100-200 μCi) and Co-57 (1-2 mCi) which furnish photons in the energy range of Mo-99 and Tc-99m, respectively, as shown in Table 6.4.

The objective of daily quality assurance testing is not to accurately assay a long-lived source; rather, it is to determine if the calibrator responds consistently from one day to the next (with a correction for decay of the long-lived source). Together, periodic calibration and routine checks of performance will assure the accuracy of measurements of activity of radiopharmaceuticals being administered clinically. Table 6.5 lists accuracy and precision data supplied by manufacturers for some commercially available calibrators.

Table 6.4. Sources for radionuclide calibrator quality control

Source nuclide	T-1/2 Principle photon	Simulated nuclide	T-1/2 Principle photon	Form	Nominal activity
Co-57	250 days 122 keV 136 keV	Tc-99m	6 hours 140 keV	vial (gel)	4-5 mCi
Cs-137	30 years 662 keV	Mo-99	67 hours 740 keV 780 keV	vial (gel)	100-200 μCi

Sources should be in solid or gel form to minimize contamination potential and inadvertent withdrawal for other uses.

Table 6.5. Performance specification of radionuclide calibrators

	Accuracy[a] (percent)	Reproducibility[a] (percent)
Nuclear-Chicago	± 5	± 3
Picker	± 5	± 3
Capintec (Squibb)	± 3	
Rad-X	± 2-10	± 2
Baird-Atomic	± 5	± 5

[a]Value for accuracy is dependent on the radionuclide and capability of supplier of radionuclide standard.

Since the predominant use of the calibrator for most nuclear medicine facilities involves assay of Tc-99m and Mo-99 breakthrough, it is advantageous to take readings of the reference source(s) at these radionuclide settings. Within limits of the reproducibility of the instrument, the readings of source(s) for a stable calibrator will then follow the characteristic half-life of the radionuclide (Payne, 1974). Progressive, or continued, outlying values indicate drift from calibration or changes in ambient conditions. Erratic readings indicate drift from calibration or changes in ambient radiation levels.

6.5.1 Procedure for Testing Reproducibility

1. Adjust the radionuclide selector dial for Tc-99m.

2. Adjust the background control until a reading of zero is obtained (if this is impossible, the background reading must be recorded).

3. Insert the Co-57 source of known activity.

4. Allow sufficient time (at least 10-15 seconds) for instrument stabilization to occur.

5. Record the reading shown on the meter (minus the background reading, if any; step 2 above) in a logbook and/or plot on a graph. (Note that the reading of the Co-57 source for the Tc-99m setting will not yield the correct amount of source activity; however, consistency of readings for the source does assure the Tc-99m setting is functioning properly.)

6. Adjust the radionuclide selector dial for Mo-99.

7. Repeat the above procedure for Cs-137 source, also recording the net reading in the logbook and/or plotting on a graph. (Note again that the reading of the Cs-137 source for the Mo-99 calibration setting will not yield the correct amount of activity for the source; however, consistency of readings for the source does assure the Mo-99 setting is functioning properly.)

8. The instrument should operate within the specifications for reproducibility given in the Operator's Manual.

6.5.2 Plotting of Calibrator Readings

The daily readings obtained from the Co-57 and Cs-137 sources should be plotted on semi-logarithmic graph paper with the reading being recorded on the logarithmic scale.

1. Calibrator readings for the two sources must be determined at the initiation of the quality control program. This is accomplished by averaging at least 10 readings taken at different times during the working day for each source. These averages become the source readings at day zero.

2. Using the accompanying decay data for Co-57 (Table 6.6), determine the activity for a selected time interval and plot this activity on the graph for the corresponding dates (see Figure 6.3). Although Cs-137 does not decay appreciably in the time span of 1 year, a decay table is given for this radionuclide and its small amount of decay during the year (Table 6.7).

Table 6.6. Decay schedule for Cobalt-57

Cobalt-57	Weeks							Half-life: 270 days		
	0	1	2	3	4	5	6	7	8	9
0	-	.982	.965	.948	.931	.914	.898	.882	.866	.815
10	.836	.821	.806	.792	.778	.764	.750	.737	.724	.711
20	.698	.686	.673	.661	.650	.638	.627	.616	.605	.594
30	.583	.573	.563	.553	.543	.533	.524	.514	.505	.496
40	.487	.478	.467	.461	.453	.445	.437	.429	.421	.414
50	.407	.400	.392	.385	.378	.372	.365	.359	.352	.346
60	.339	.333	.327	.322	.316	.310	.305	.299	.294	.289
70	.284	.279	.274	.269	.264	.259	.254	.250	.245	.241
80	.237	.233	.229	.224	.220	.217	.213	.209	.205	.201
90	.198	.194	.191	.187	.184	.181	.178	.174	.171	.168

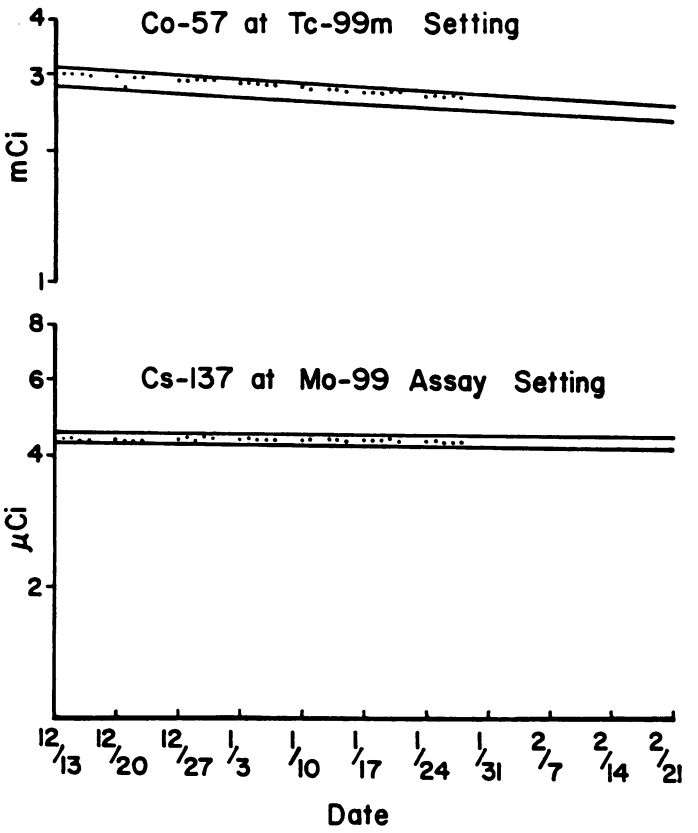


Figure 6.3. Calibrator quality control graph.

Table 6.7. Decay schedule for Cesium-137

Cesium-137	Months								Half-life: 30 years			
	0	1	2	3	4	5	6	7	8	9	10	11
0	-	.998	.996	.994	.992	.990	.989	.987	.983	.983	.981	.979
1	.977	.975	.973	.972	.970	.968	.966	.964	.962	.960	.959	.957
2	.955	.953	.951	.949	.948	.946	.944	.942	.940	.938	.937	.935
3	.933	.931	.929	.928	.926	.924	.922	.921	.919	.917	.915	.913
4	.911	.910	.908	.906	.905	.903	.901	.900	.898	.896	.894	.893

3. The errors in the instrument readings are determined by the product of the source reading and the repeatability of the individual calibrator. The error should be determined for the initial reading and for the expected calculated reading for 1 year. A straight line should be drawn connecting the upper and lower limits of the errors for the respective initial and final readings (see Figure 6.3).

4. The daily readings of the check sources should fall within the lines drawn in step 3. If a reading falls outside the expected range, the reproducibility of the instrument is suspected, and the responsible individual in the laboratory should be contacted immediately.

6.5.3 Quarterly Inspections

The calibrator should be inspected on a quarterly basis to ascertain that the chamber liner is in place and that the instrument's zero adjustment is properly set (see manufacturer's instructions) (NRC, 1980). Also, on a quarterly basis, measure the apparent activity of a long-lived standard radionuclide such as Cs-137 or Ra-226 at all of the commonly used radionuclide settings and compare them to the initial readings recorded with this source at these settings (when the unit was first calibrated against NBS-traceable standards) (NRC, 1980).

Radionuclide calibrators are instruments that require regular checks and proper usage to assure that they are operating correctly. As with any instrument, knowledge of calibrator operation will ensure its most accurate and efficient use. If the tests outlined here are performed as indicated in Table 6.8, a calibrator can be used confidently to obtain correct assays of the activity of radiopharmaceuticals prior to administration.

Table 6.8. Testing for radionuclide calibrators

Test	Frequency			
	Daily	Quarterly	Annually	Initially
Repeatability	x			
Zero setting		x		
Inspection of liner		x		
Relative response to reference source		x		
Linearity of response		x		
Accuracy (calibration)			x	
Geometry effects				x

REFERENCES

American National Standards Institute. Calibration and Usage of "Dose Calibrator" Ionization Chambers for Assay of Radionuclides. ANSI N42:13, 1978 (Institute of Electrical and Electronics Engineers, Inc.) New York (1978).

Dubuque, G.L., R.J. Grant, J.G. Kereiakes, and R.J. Van Tuinen. Measuring Mixed Energy Gamma Radionuclides Using a Radionuclide Calibrator. Int J Nucl Med Biology 3, 145 (1976).

Genna, S., E.W. Webster, J.C. Brantley, et al. A Nuclear Medicine Quality Control Program. J Nucl Med 13, 285 (1972).

Hare, D.L., W.R. Hendee, W.P. Whitney, and E.L. Chaney. Accuracy of Well Ionization Chamber Isotope Calibrators. J Nucl Med 15, 1138 (1974).

Joint Commission on Accreditation of Hospitals. Nuclear Medicine Services: Accreditation Manual for Hospitals. JCAH, Chicago (1980).

Payne, J.T., M.K. Loken, and R.A. Ponto. Comparison of Dose Calibrators for Radioactive Assay. J Nucl Med 15, 522 (1974).

U.S. Department of Health, Education and Welfare (USDHEW), FDA, Workshop Manual for Radionuclide Handling and Radiopharmaceutical Quality Assurance (Draft) (April 1977).

U.S. Nuclear Regulatory Commission. NRC Regulatory Guide 10.8: Guide for the Preparation of Applications for Medical Programs. NRC, Washington, D.C. (1980).

United States Pharmacopeia XIX. United States Pharmacopeia Convention, Inc. (USPC), Rockville, MD (1980).

7. ADMINISTRATION OF RADIOPHARMACEUTICALS TO PATIENTS

Hiroshi Nishiyama
Nuclear Medicine Laboratory, DEP, BRH, FDA
Cincinnati, Ohio

7.1 PERSONNEL EXPOSURE IN ADMINISTERING RADIOPHARMACEUTICALS

An understanding of how personnel radiation exposure occurs is basic to any effort to lower it. Even though one may handle a large quantity of radiopharmaceuticals, the exposure to the handler can still be quite low if these materials are adequately shielded. To determine the amount of radiation exposure from the dosage preparation, assay, injection and imaging procedure, a study based on observations at three hospitals was conducted at Stanford University (Barrall, 1976). These data are shown in Table 7.1.

The data recorded are for procedures of average difficulty on typical adult patients. Syringe shields were used for all injections. Studies on difficult patients, such as children, persons with mental problems or those with inaccessible veins may easily result in radiation exposures significantly higher than those shown in the table.

The significant difference in total exposure from bone scans obtained with a rectilinear scanner as compared with a camera (0.09 vs. 0.57 mR, respectively) is an interesting example of specific equipment affecting radiation exposure. The additional exposure in obtaining images with the camera results primarily from frequent repositioning of the patient to obtain a series of views.

In the last column of Table 7.1, the percentage of exposure from imaging is listed. Generally, the exposure from imaging is a major fraction of the exposure from the entire procedure. The two exceptions are cerebral blood flow and lung ventilation studies. The imaging for a cerebral blood flow study usually requires only a few minutes. The lung ventilation procedures studied in this report employ an aerosol produced in a nebulizer. In this procedure there can be significant exposure during the dose preparation because of the great quantity of activity handled. The requirement to clean up the apparatus from a prior patient will add further exposure.

Thus, the data in Table 7.1 show that, in nuclear medicine laboratories having good radiation safety practices, the most significant source of exposure is generally the radiation emanating from the patient during the imaging procedure.

The amount of exposure received in any given procedure can vary considerably depending upon several factors such as:

1. The ability of the patient to cooperate and the consequent need for attention to the patient.

2. The number of views obtained.

3. The activity and type of radiopharmaceuticals administered.

4. The size and layout of the laboratory space.

5. The type of equipment used for imaging.

Table 7.1 Typical exposure to technologists from selected procedures

Procedure	Typical activity injected (mCi Tc-99m)	Typical exposure at body position (mR) Dose preparation and assay	Injection	Imaging	Total	Precentage of exposure from imaging
Brain	20	0.04	0.02	0.22	0.28	79
Cerebral blood flow (CBF)	20	0.04	0.02	0.03	0.09	33
CBF and brain	20	0.04	0.02	0.25	0.31	81
Liver and spleen	4	0.01	0.01	0.03	0.05	60
Bone scan (rectilinear scanner)	15	0.02	0.01	0.06	0.09	67
Bone scan (camera)	15	0.02	0.01	0.54	0.57	95
Lung ventilation (aerosol)	30 (3 mCi inhaled)	0.12	0.08 (inhaled)	0.09	0.29	31
Thyroid	2	0.02	0.01	0.04	0.07	57
Myocardium	15	0.01	0.01	0.02	0.04	50
Angio	10	0.02	0.01	0.04	0.07	57

Since the patient is a source of radiation, the imaging time and the distance from the patient become two important factors in determining the amount of radiation exposure. The individual laboratory must cope with the available space and equipment in order to minimize personnel exposure. Routine procedures that will allow greater distances between the personnel and the patient and will promote time saving as well should be developed with careful planning and practice. Specific needs and innovations may be governed by the space available. The following are merely suggestions:

1. Various head-holding devices are available for brain studies. Tape-strapping is also effective if the patient is cooperative. Concave-shaped sponge pillows can hold the patient's head in the supine position. Avoid holding the patient's head unless this is necessary.

2. Many modern scintillation cameras are equipped to sequentially image the whole body with remote-controlled moving devices. If this capability is available, it should be fully utilized when needed. Its effect in reducing radiation to personnel is similar to that of the rectilinear scanner as compared to the scintillation camera (see Table 7.1).

3. Devices are available commercially to immobilize the entire body of infants and small children; these can also be used for adults in certain situations.

Repeated imaging procedures can be kept to a minimum if the technique is correct. Quality control measures and a thorough knowledge of instrumental functions are essential to achieve this goal. The size and layout of a laboratory, the type of instruments and procedures used, and the cooperativeness of the patient, all are factors governing the necessary distance between the technologist and the patient. This distance should be kept as great as practicable.

7.2 SHIELDING

The importance of reduced imaging time and increased distance from the patient have already been discussed in this chapter. Another important factor in reducing radiation exposure to personnel is the use of shielding. These factors are also discussed in Chapter 5.

7.2.1 Shields for Drawing Dosages

Drawing dosages should be accomplished behind a shielded work station. When attempting to observe the volume of material drawn into the syringe, the radiation level to the eyes can be at significantly high levels. Typical eye exposure rates per mCi of various radionuclides are given in Table 7.2 (USDHEW, 1977).

Vials with high radionuclide content should never be handled without being covered by a shield. During the dosage- drawing procedure, either syringe shields or syringe holders should be available for use. This will further reduce the exposure to the fingers. Exposures during dosage-drawings in a typical laboratory have been estimated to be 8 mrem/day when using syringe shields and 40 mrem/day when the syringes are not shielded (Williams, 1979).

Table 7.2 Eye exposure rates from various radionuclides

Radionuclide	mR/hr-mCi at 15 cm
Technetium-99m	3.1
Iodine-131	9.7
Xenon-133	3.1
Molybdenum-90	5.7
Mercury-230	5.3
Selenium-75	7.7
Ytterbium-169	4.0

7.2.2 Syringe Shields

Handling of radiopharmaceuticals in an unshielded syringe can result in a high radiation exposure rate to personnel. Estimates of 600 to 1100 mR/hr-mCi (for the index finger of the hand) are realistic and should be of concern to personnel in a nuclear medicine laboratory (Barrall, 1976).

Syringe shields of various types are available commercially, but few,thus far, are satisfactory in terms of their design, serviceability, and cost. A simple type of lead shield with a lead-glass window, which allows the syringe to be slipped in and out, is inexpensive and is adequate for most purposes when using 3 to 5 cc syringes; however, most of these types will not accommodate a 1 cc tuberculin syringe without requiring the needle cover to be removed, and this increases the probability that nonsterile and pyrogenic conditions may develop.

The bulkiness and added weight of the syringe shield may give some difficulty in administering radiopharmaceuticals. However, a survey made among physicians and technicians showed essentially no difference in the time needed for injection, with or without the syringe shield (Branson, 1976). The bulkiness gives a slight psychological drawback to the user, but this can be overcome after several uses. The use of syringe shields have been demonstrated to reduce exposure levels by a factor of 3 or more (Branson, 1977).

7.2.2.1 Use of Syringe Shields

If the prepared radiopharmaceutical is kept in a shielded vial and is withdrawn at each administration, the following steps are suggested:

1. Calculate the desired volume of the radiopharmaceutical to be withdrawn.

2. Prepare the syringe with a tightly secured needle; Luer-locking syringes are the best.

3. Withdraw the calculated volume behind an appropriate shield.

4. Transfer the loaded syringe immediately to the calibrator for assay. If the location of the calibrator is distant, carry the syringe in a shielded container.

5. After assay, insert the syringe into the syringe shield and secure tightly.

6. Place into a tray, or a shielded carrier for transportation (see 7.3).

If transparent and/or retractable syringe shields are used, steps 3 and/or 4 can be performed with the syringe in the shield.

The minimum number of syringe shields required depends upon the size of operation; however, it is preferred that each technologist have her/his own syringe shield. In addition, some spares should be available in the laboratory in case of loss or malfunction. Because of the possibility of contamination, empty syringe shields should not be kept in pockets.

7.3 TRANSPORT OF RADIOPHARMACEUTICALS TO PATIENTS

A washable tray of either stainless steel or ceramic-coated steel, both covered with plastic coated absorbent paper, should be used for transporting radiopharmaceuticals. The assayed and properly shielded, loaded syringe should be transported in the tray along with a pair of disposable gloves, a small plastic bag, a few cotton swabs, dry sponges, and a tourniquet. The small plastic bag is needed to contain the used syringe and all other used materials for disposal. It is recommended that only the necessary quantity of cotton swabs, gloves, and dry sponges be kept on the tray to prevent contamination of unused material. The tray should be prepared each time in order to avoid cross contamination. If the prepared radiopharmaceuticals are to be transported from the laboratory to some other area, the container should be adequately shielded. A box-type carrier is convenient for this purpose.

7.4 CONTAMINATION CONTROL

Protection from contamination and unnecessary radiation exposure relies upon the use of proper procedure during the radiopharmaceutical handling and skill of the personnel. In either case, the goal of contamination control will not be achieved without careful practice and the use of protective measures at all times.

7.4.1 Gloves

The most effective means of keeping the skin free of radioactive contamination is through the use of disposable gloves. They should be worn any time a radiopharmaceutical is handled; there are no exceptions. Because of possible contamination of the gloves during a procedure, they should be discarded as soon as the procedure is complete. One pair of gloves should not be used from one procedure (administration) to another. When removing gloves, pull them off inside-out, i.e., the contaminated outside is now on the inside. This should lessen the risk of further contamination.

7.4.2 Clothing

Contamination of clothing should not occur if proper care is exercised; however, the possibility does exist (Nishiyama, Lukes, and Feller, 1980). Wearing a knee length, long sleeve laboratory coat should eliminate contamination of personal clothing. If the coat worn during these procedures becomes contaminated, it should be taken off and put in a plastic bag and placed in the storage area until the radionuclide decays. Uniforms, such as the female nursing type, without an outer lab coat, are not ideal clothing when handling radiopharmaceuticals.

7.4.3 Exposure and Contamination Monitoring

Laboratory personnel working with radioactive materials should routinely monitor themselves for contamination. Inspection of the hands with a radiation monitor should be performed as often as possible, especially after each dosage withdrawal and administration of a radiopharmaceutical (Nishiyama, Van Tuinen, 1980). Hands should not be used to answer telephone, open doors, etc., before they are checked for contamination. Before leaving the nuclear medicine area to go to lunch, coffee break, etc., and at the end of the day, the hands and clothing should be monitored for contamination.

Eating is not allowed in those areas where radionuclides are being stored or handled, and food should never be placed in a refrigerator containing radioactive material.

A personnel monitor should always be worn and dosimetry reports should be reviewed by the Radiation Protection Officer to evaluate the need for corrective action. Personnel administering radiopharmaceuticals may wear ring TLD's in addition to whole body monitors. If the individual's dosimetry report is limited to the single body monitor, it is easy to be deceived into a sense of false security since hand exposures can be significantly higher than total body exposures. Laboratory personnel should keep in mind when handling tens or hundreds of millicuries of radioactivity daily, that one or two ill-conceived procedures during a month can place your hand exposure close to the maximum permissible level of 18.75 rems/quarter (CFR, 1980).

7.5 RECORDS

Accurate recording of all radionuclide transfers and radiopharmaceutical administrations is essential for the safety of laboratory personnel and patients. The system must be sufficient to allow accountability for all radioactive materials regardless of their stage of preparation. A detailed description of record keeping and inventory of radioactivity is given in Chapter 4.

The following are suggestions for recording administrations:

1. Master logbook: All radioactive material received in the laboratory must be recorded with date, time, name of radionuclide, and its activity at calibration time, and handler's name.

2. Radiopharmaceutical logbook: The prepared batch of radiopharmaceutical should be adequately labeled and recorded in the logbook. Date, name of radiopharmaceutical, time of calibration, total activity, volume in ml, and name of preparer should be recorded for the individual dosage drawn.

3. Patient dosage logbook: When drawing a patient dosage, be sure the desired batch of radiopharmaceutical is labeled on the bottle. Calculate the desired activity per volume, draw the dosage into the syringe, assay and place it into the syringe shield. Record the date, time of calibration, name of radiopharmaceutical, amount of activity and volume, name of patient, and handler's name. The practice of countersigning by

two persons (one preferably a physician) when dealing with therapeutic quantities of radionuclides, such as I-131, is strongly recommended.

Each patient's dosage is recorded in the laboratory logbook. However, it is also necessary to record the name and quantity of the radiopharmaceutical administered in the patient's nuclear medicine chart or report sheet that will eventually be added to the patient's record. If the patient is in the hospital, it is recommended that the name and quantity of the radiopharmaceutical given be recorded in the hospital chart.

7.6 ADMINISTRATION PROCEDURE

The radiopharmaceuticals most commonly used for diagnostic procedures are Tc-99m-labeled compounds, Ga-67 citrate, Tl-201 chloride, I-131-hippuran, and In-111-DTPA. These radiopharmaceuticals are generally administered intravenously. On the other hand, both I-123 (sodium chloride) and Co-57-B_{12} are usually supplied in capsule form for oral administration and, hence, involve minimal handling problems. The therapeutic dosage of I-131 and some diagnostic doses of both I-131 and I-123 are given orally in liquid form or as capsules. All of these modes of administration will be discussed in this section. The administration of either Xe-133 or Xe-127 will be discussed in Section 7.7.

7.6.1 Intravenous Administration

The following are suggested practices that should minimize the expenditure of time during intravenous administrations:

1. Examine the best available vein with the tourniquet on. This step should be done before putting on gloves since a deepseated vein can be felt better without them.

2. Wear gloves and swab the skin thoroughly.

3. Inject the prepared dosage with the syringe in a shield.

4. Withdraw the needle and press the point of injection with a dry sponge. Hemostasis can be far better achieved with a dry sponge than with a wet cotton swab. If possible, let the patient press the top of the dry sponge lightly.

5. Put all the used materials into the plastic bag, or put the syringe separately in a small plastic bag and the rest can be put into the glove when it is pulled inside out in the manner described above.

Used gloves, swabs, sponges, and in particular, syringes are all considered as sources of contamination. It is not unusual for the syringe to have residual activity of close to a mCi level when a radionuclide of high specific activity is employed.

7.6.2 Calibration and Assay for Oral Administration

Most oral administrations in nuclear medicine involve the use of Co-57-B_{12}, I-123 and I-131 in capsular or liquid form. The concern in handling open containers of radioactive liquids is that they are not spilled, and in the case of volatile materials, such as the radioiodines, that they do not present airborne contamination problems. Thus volatile radioactive materials should be handled in a hood (Nishiyama, Lukes, and Mayfield, 1980). The storage of I-131, especially at therapeutic dosage quantities, must be secured by both adequate shielding and ventilation at all times.

Therapeutic amounts of I-131 should not be handled directly with the hands. The recommended step-wise procedure for the proper handling of I-131 is summarized as follows:

1. Check the logbook and be sure of the I-131 activity per given volume with decay correction.

2. Calculate the desired amount of the therapeutic dosage by volume.

3. Working in a lead-shielded,ventilation hood, using a remote device, pipet the aliquot of I-131 into a prepared container in a lead vial shield.

4. Assay the activity using long forceps.

7.6.3 Oral Administration of I-131 for Hyperthyroidism

1. Place the lead-shielded container of I-131 on a surface behind an additional lead shield. It is preferable that this lead shield be hooded and ventilated into a filter for volatile materials (Nishiyama, Lukes, and Mayfield, 1980).

2. Have the patient sit on the side of the shield with the I-131 and swallow the dosage using a straw.

3. Add water to the drained container and have patient swallow entire contents. Do this step three times.

At no time should the straw or container be touched by anyone's hands. Again, the area should have adequate ventilation and upon completion of the administration, the patient should not be allowed to stay an unnecessary length of time since the patient is now the source of radiation.

7.6.4 Oral Administration of I-131 for Thyroid Carcinoma

The prescribed dosage of I-131 for the treatment of thyroid carcinoma could be 10 to 20 times higher than that for hyperthyroidism. It may range from 70 to 200 mCi in a single dosage. Therefore, extra precautions must be exercised. Because of the high activity, this therapeutic dosage cannot be administered to an outpatient.

The patient must be isolated, preferably in a room at the extreme end of the building with the bed positioned close to the outside wall. If the room is in the middle of the ward, the bed should be set as far away from the corridor and away from either side wall as possible to avoid exposure to others in adjacent areas.

The cancer therapy dosage should be brought to the patient's room shielded with 2-inch lead bricks on a cart with a long handle. Use of an ordinary lead-pig to contain the dosage is inadequate. The dosage should be administered by the same procedure described in 7.6.3. At all times, direct handling must be avoided.

Usually the patient has already undergone thyroidectomy before being given a cancer therapy dosage of I-131. If this is the case, over half of the activity will be excreted in the first 24-hour period, mainly in the urine. Thus, the patient can be discharged at the end of the second or third 24-hour period after the treatment if the remaining activity in the body is no more than 30 mCi.

Special precautions should be taken in the disposal of urine from patients who have received therapeutic dosages of I-131. A procedure that is used at the University of Cincinnati (1978) employs a radioiodine cleaning solution. Whenever the patient goes to the bathroom, 1 ounce of the radioiodine cleaning solution is added to the toilet (or bedpan) before using. The toilet (or bedpan) is allowed to stand for 2 minutes after use and then flushed 3 times. The radioiodine cleaning solution consists of 4 gm potassium iodide to 1 liter of water.

7.7 XENON GASES

Xenon is used primarily in the gaseous form and its handling requires some considerations other than previously described. The use of Xe-133 is common and that of Xe-127 is increasing. Their biological properties are identical, but their varying physical characteristics require that they be handled differently.

Xenon gas is heavier than air, but once dispersed, it will remain uniformly distributed. If a good ventilation system exists in the room, the room air should not be seriously contaminated during a routine Xe-133 ventilation study (Nishiyama, 1982). Xenon-133 has a physical half-life of 5.3 days and its energy is 81 keV. These characteristics make both shielding and disposal relatively easy. On the other hand, Xe-127 has a physical half-life of 36.4 days and its photon energies range from 58 to 375 keV, with the main energy at 203 keV in 68 percent abundance. The long physical half-life and high energies require different shielding, storage, and handling than the Xe-133.

7.7.1 Supply and Storage

Commonly, Xe-133 is supplied in individual dosages (10-20 mCi quantities) in a lead-shielded vial. Because its 81 keV photons are adequately stopped by the shield, the xenon can be stored in a hood until time of administration. A bulk supply of Xe-133 containing Ci amounts can also be purchased. This quantity is usually supplied in a crushable ampule, and requires a xenon gas dispensing system. If more than two or three xenon ventilation studies are done daily, a bulk supply of Xe-133 may be more economical than the 10-20 mCi vial system. The xenon dispensing system is adequately shielded; however, a potential leak is always possible. Thus, the dispenser should be placed in an isolated room that is well ventilated.

Xenon-127 is now available from some national laboratories and radiopharmaceutical manufacturers. Currently, the gas is supplied only in the crushable ampule and, hence, a xenon dispensing system is required. If a xenon dispenser system designed for Xe-133 is used, additional lead shielding must be placed around the system prior to use with Xe-127. Again, the dispenser should be placed in an isolated room where ventilation is available.

7.7.2 Dispensing and Trapping

If Xe-133 is obtained in the form of a unit dosage, users must have their own delivery system. These are either the pistol or crushable ampule type.

Some xenon systems are available commercially for single breath ventilation studies. When the washout phase starts, a built-in trapping system becomes operational.

All commercially available xenon trapping systems, whether the built-in type just mentioned or the separate units, have activated charcoal as the collecting agent. It has been claimed that the trap will operate at an average efficiency of 95 percent (McIlmoyle, 1978). The activated charcoal in the cartridge must be replaced periodically. The charcoal degeneration is difficult to predict because of various regional and laboratory factors. While one may wish to rely on each manufacturer's suggestion of the average lifetime of the trap, if a counting system is available, the exhaust air coming out of the air-outlet of the trapping system can be monitored to determine the extent of radiation leakage (Nishiyama, 1982).

The maximum permissible concentration of Xe-133 in air of a restricted area is 1×10^{-5} μCi/ml. An unrestricted area must have less than 3×10^{-7} μCi/ml.

7.8 DISPOSAL

Materials used in the administration of radiopharmaceuticals to patients must be disposed of properly since they are a source of radiation. Exceptions here are the tourniquet and syringe shield, which should be frequently monitored for possible contamination. If gross contamination is found, the items should either be decontaminated or set aside for adequate decay.

Also available commercially are inexpensive xenon ventilation systems, which can be disposed of at the end of the study if no xenon-contaminated air remains in the system. Upon completion of the ventilation study, residual xenon in the disposable system must be thoroughly blown out into an exhaust vent or trapping system.

Disposal of radioactive waste is discussed in Chapter 9.

7.8.1 Short-Lived Radionuclides

From a practical standpoint, short-lived radionuclides should be considered to be those with half-lives comparable to Tc-99m (6 hrs) or less. The used syringes, alcohol swabs, gloves, sponges, etc., should be placed in plastic bags or rubber gloves (see Section 7.6.1) for disposal. The container for disposal of contaminated materials should be adequately shielded. A metal trash can with a foot-pedal device for opening the top is ideal. The inside should be permanently lined with a lead-sheet and with a disposable plastic bag.

If no additional contaminated materials are disposed of after Friday evening, the plastic liner bag containing used syringes can be safely disposed of as normal waste on the following Monday. All waste should be monitored before placing in the normal waste disposal.

7.8.2 Long-Lived Radionuclides

Long-lived radionuclides are defined as having half-lives longer than that of Tc-99m. Frequency of the use of these radionuclides is far less than Tc-99m-compounds, but their potentials as a health hazard can be far greater because of their longer physical half-lives. The straw and container used for I-131 therapeutic purposes should be especially considered in this category. It is difficult to estimate time for safe disposal of these materials because I-131, Ga-67, Tl-201, In-111, etc., can all be included here. All disposal systems (trash cans, plastic bags, etc.) must be monitored before this type of waste can be disposed of (see Chapter 9).

REFERENCES

Barrall, R.C. and S.I. Smith. Personal Radiation Exposure and Protection from Tc-99m Radiation. In Biophysical Aspects of the Medical Use of Technetium-99m, Kereiakes J.G., and Corey K.R., eds. AAPM Monogram, No. 1. AAPM, University of Cincinnati (1976).

Branson, B.M., V.J. Sodd , H. Nishiyama, and C.C. Williams. Use of Syringe Shields in Clinical Practice. J Clin Nucl Med 1,56 (1976).

Branson, B.M., V.J. Sodd, C.C. Williams, H. Nishiyama, R.J. Van Tuinen, and J.G. Kruger. Selection Criteria for Syringe Shields. Proceedings of the 18th Annual Meeting of the Southeastern Chapter of the Society of Nuclear Medicine, Winston-Salem, North Carolina, (1977).

Code of Federal Regulations, Title 10 Energy (10 CFR) Office of the Federal Register (Washington, D.C.: U.S. Government Printing Office), 1980.

McIlmoyle, G., B.L. Holman, M. Davis, and H.L. Chandler. A Portable Radioxenon Trap and Patient Ventilation System. Radiology 127, 544 (1978).

Nishiyama, H, S.J. Lukes, P.A. Feller, R.J. Van Tuinen, and E.L. Saenger. Survey of 99m-Tc Contamination of Laboratory Personnel: Its Degree and Routes. Radiology 135, 467 (1980).

Nishiyama, H., R.J. Van Tuinen, S.J. Lukes, and P.A. Feller. Survey of 99m-Tc Contamination of Laboratory Personnel: Hand Decontamination. Radiology 137, 549 (1980).

Nishiyama, H., S.J. Lukes, G. Mayfield, and L.W. Grossman. Internal Contamination of Laboratory Personnel by I-131. Radiology 137, 767 (1980).

Nishiyama, H., and S.J. Lukes. Exposure to Xe-133 in the Nuclear Medicine Laboratory. Radiology (to be published) (1982).

University of Cincinnati, Radiation Safety Committee, Radiation Safety Manual, University of Cincinnati (1978).

U.S. Department of Health, Education, and Welfare (USDHEW), FDA, Workshop Manual for Radionuclide Handling and Radiopharmaceutical Quality Assurance (Draft),(April 1977).

Williams, C.C., V.J. Sodd, and B.M. Branson. Evaluation of Radiation Exposure from an Automated Tc-99m Dispensing System. J Nucl Med Tech 7, 23 (1979).

8. HANDLING PATIENTS AFTER ADMINISTRATION OF RADIOPHARMACEUTICALS

Jeannine T. Lewis
Office of the Bureau Director, BRH, FDA
Rockville, Maryland

8.1 INSTRUCTIONS TO PATIENT

In any nuclear medicine procedure, whether diagnostic or therapeutic, it is important that the patient have a thorough understanding of the procedure prior to the administration of the radiopharmaceutical, particularly when a procedure requires patient participation. A few moments spent in explanation will allay the fears of most patients and thereby gain their cooperation.

The majority of radiopharmaceutical administrations for diagnostic procedures are by intravenous injection. The patient should be assured that the only discomfort that will be experienced is from the injection itself. During the injection, precautions must be taken that none of the material spills on the patient's skin and that the needle is indeed in the vein before the injection is begun.

At times a patient will receive a radiopharmaceutical orally, either in a capsule or in liquid form. Care must be taken that the patient actually swallows the material and that none of the liquid is permitted to spill. Both inpatients and outpatients should be instructed to report if vomiting occurs after oral administration. In the case of a diagnostic dosage, this precaution is necessary not only because of the contamination problems but also because the loss of administered tracer would probably require readministration.

Administration of gaseous radiopharmaceuticals, as in lung ventilation studies, requires particular care. It is in this situation that patient instruction and cooperation are especially important. Care must be taken to insure that the breathing and trapping systems do not leak. The patient must remain attached to the breathing system until the washout phase is completed.

Each administered dosage must be entered in the patient's record. Technologists receive some exposure when imaging such patients. This exposure increases with time spent in proximity to the patient and with increasing patient load (Harbottle, 1976). (See also discussion in Section 7.1).

8.2 INSTRUCTIONS TO NURSING STAFF

Nurses caring for patients who have received diagnostic dosages of radiopharmaceuticals should be told that they will receive insignificant radiation exposure in carrying out normal nursing care. No special precautions are needed for dishes, instruments or utensils. Visitors are permitted in accordance with hospital rules (Quimby, 1960). Instructions to the nursing staff handling patients who have received therapeutic dosages are discussed in Section 8.3.

Some diagnostic procedures may require the collection of excreta. Nurses should wear rubber gloves when handling specimens or soiled linen. If the patient should vomit or contaminate the bed with urine or feces, particularly during the first 24 hours following administration, the institution's Radiation Protection Officer should be called to monitor the linen for proper disposal. Today's common practice of administering multimillicurie dosages of Tc-99m for diagnostic tests poses a potential contamination hazard. Nurses

caring for patients receiving such levels should be instructed that a hazard exists in the event of spillage or incontinence (Reece, 1976).

8.3 THERAPY PATIENTS

In the case of the therapeutic dosage, the risk of radioactive contamination is greatly increased. Patient understanding and cooperation must be gained prior to administration of the therapy dosage. The patient should be told ahead of time if they will be allowed to return home or if they will be required to remain in the hospital. In either case, they must thoroughly understand any precautions pertaining to their particular therapeutic procedure.

8.3.1 Outpatients

In this country, it is required that patients be hospitalized until their content of any radioactive material is less than 30 millicuries (NCRP, 1970). The administration of a therapeutic dosage should be documented in the patient's clinical record, whether the patient is an inpatient or an outpatient.

Many times, patients receiving radioiodine therapy are allowed to return to their homes. These patients should know who to contact if vomiting occurs within 1 hour (Quimby, 1960). Also, these patients are advised to sleep alone for 2 weeks, to use separate toilet facilities where possible, and to use stringent contraceptive measures to avoid pregnancy during the month and a half following treatment (University of Cincinnati, 1978).

A 1978 investigation indicated that some radioiodine transfer does occur between patient and family, particularly between parent and child. The two principal factors cited are the proximity between patient and child and the relatively high radioiodine activity of body fluids (Jacobson, 1978).

8.3.2 Inpatients

Hospitalized patients that have been administered radioactive materials require special precautions in their care. The length of time that nurses, housekeeping personnel, and other hospital staff may spend in caring for these patients depends upon the exposure they may receive. Table 8.1 lists approximate times for exposure of 100 mR from 100 mCi of various radionuclides. This is taken from NCRP Report No. 37 and is considered to be conservative in its approximations. Nurses should be instructed to perform patient care as expediently as possible. Pregnant nurses should not be responsible for routine care of patients receiving therapeutic dosages (NCRP, 1970). During the entire gestation period, the maximum permissible dose equivalent to the fetus from occupational exposure of the expectant mother should not exceed 0.5 rem (NCRP, 1971).

Table 8.1. Approximate times for exposure of 100 mR from 100 mCi of various radionuclides at specified distances

Radionuclides	Approximate time for 100mR per 100 mCi	
	at 2 feet (0.61 meter)	at 6 feet (1.83 meters)
	hours	hours
Chromium-51	25	230
Iodine-125	12	115
Iodine-131	1.5	15

8.3.3 Collection of Excreta

Some institutions require the collection of urine for a specified time after radioiodine therapy. In these cases, patients should be encouraged to collect their own urine. If the nurse must handle the urine container, rubber or plastic gloves should be worn. In the case of vomiting or urinary incontinence within the first 48 hours, all contaminated materials must be handled with rubber gloves. In any such occurrence, the Radiation Protection Officer must be notified.

Patients receiving therapeutic dosages intraperitoneally require no special precautions for excreta. However, surgical dressings should be checked frequently for drainage. Any time such drainage is noted, the physician and the Radiation Protection Officer must be notified immediately. Dressings and bandages should be changed only as directed by the physician (NCRP, 1970).

If there is any doubt whatsoever that accidental contamination has resulted from any cause, the Radiation Protection Officer must be notified immediately. The area should be isolated and precautions taken to prevent the spread of contamination.

8.3.4 Restrictions on Visitors and Roommates

Generally speaking, there is no need to restrict the number of visitors to therapy patients. The maximum permissible dose for this category of persons is 500 mrem per year, and there is little likelihood of visitors exceeding this dose. Visitors should be advised to remain at least 6 feet from the patient. Brief periods of contact during greeting are permitted. Children and pregnant women should not be permitted to visit patients who have received high therapeutic dosages. Exceptions may sometimes be made, but the visits should be brief and maintained at a distance of at least 6 feet.

It is preferred that other patients not be placed in the room with a radioactive patient as they will receive some exposure also. If done, these other patients should receive a dose equivalent of not more than 100 mrem from a radioactive patient during any one hospital confinement (NCRP, 1970). An estimation of the exposed patient's dose should be entered in the patient's clinical record.

8.3.5 Discharge of the Patient

Therapy patients are generally not released from the hospital until their radioactivity content is less than 30 millicuries (NCRP, 1970). Certain exceptions may, however, be granted. In these cases, it is necessary to meet certain criteria, namely:

1. No person in the household under 45 years of age shall receive greater than 0.5 rem/year.

2. No person in the household over 45 years of age shall receive greater than 5 rem/year.

3. The reason the exception was made must be documented.

4. The local health authorities must be notified (NCRP, 1970).

Table 8.2 presents reasonable limits for discharge of radioactive patients from the hospital (NCRP, 1970). One should note that longer distances and shorter times lead to less exposure. Anytime therapy patients are discharged, it must be entered in their record. Any special instructions should be given to the family of the released patient.

Table 8.2 Radioactivity levels for discharge of radioactive patients from hospital

Radionuclide	No restrictions		All persons in household over 45 years of age[a]		Some members of household under 45 years of age[b]	
	Exposure rate at 1 meter (mR/h)	Activity at discharge (mCi)	Exposure rate at 1 meter (mR/h)	Activity at discharge (mCi)	Exposure rate at 1 meter (mR/h)	Activity at discharge (mCi)
Cr-51	0.5	35	5	350	1.5	100
I-125	0.2	8-80[c]	2	20-800[c]	0.6	20-250[c]
I-131	1.8	8	18	80	11	50

[a]These levels are in general higher than any likely to be encountered.

[b]These values are rather arbitrarily selected on a basis of the probability of the situation. They represent complete integrated doses of between 1.5 and 2.5 R.

[c]These values cover a large range, because of the variable attenuation of the 35-keV x rays in the patient.

REFERENCES

Harbottle, E.A., R.P. Parker, and R. Davis. Radiation Doses to Staff in a Department of Nuclear Medicine. Br J Radiol 49, 583 (1976).

Jacobson, A.P., P.A. Plato, and D. Toeroek. Contamination of the Home Environment by Patients Treated with Iodine-131: Initial Results. AJPH. 68, 225 (1978).

National Council on Radiation Protection and Measurements. NCRP Report No. 37: Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides. NCRP, Washington, D.C. (1970).

National Council on Radiation Protection and Measurements. NCRP Report No. 39: Basic Radiation Protection Criteria. NCRP, Washington, D.C. (1971).

Reece, B.L. and P.J. Roberts. Radioactive Contamination Hazards From Patients. Br J Radiol 49, 584 (1976).

Quimby, E.H. Safe Handling of Radioactive Isotopes in Medical Practice. The MacMillan Co., New York (1960).

University of Cincinnati, Radiation Safety Committee, Radiation Safety Manual. University of Cincinnati (1978).

9. WASTE DISPOSAL REGULATIONS

Kenneth L. Scholz
Nuclear Medicine Laboratory, DEP, BRH, FDA
Cincinnati, Ohio

In general, because of the short half-lives of radioactive materials used in nuclear medicine laboratories, the majority of radioactive waste can be properly stored and left to decay and disposed of as normal trash as explained below; or it can be returned to the manufacturer as in the case of spent Mo-99-Tc-99m generators. However, unneeded radionuclides disposed of at a nuclear medicine laboratory must be in accordance with Nuclear Regulatory Commission (NRC) and/or State regulations. This chapter demonstrates disposal regulations as they apply to a nuclear medicine laboratory.

In non-Agreement States, the NRC regulates "byproduct" (reactor produced), "special nuclear material," and source material and the State has the responsibility to control all other radioactive materials. In States having an agreement (currently 26; see Table 1.1) with the NRC, control of radioactive materials is performed by the State; however, most State regulations correspond closely to those of the NRC.

9.1 NUCLEAR REGULATORY COMMISSION

Federal regulations established by the NRC for the disposal of radioactive materials are contained in the Code of Federal Regulations, Title 10 (10 CFR) Part 20.301-305. Under specified conditions, the following methods of disposal are suitable:

1. Transfer to an authorized recipient.
2. Release into a sanitary sewer system.
3. Burial in the soil.
4. Other methods approved by NRC following specific application.

A fifth method - storage of material for decay until it emits negligible radiation, then disposal by conventional methods - is described in other NRC guidelines (Guide for Preparation of Applications for Medical Programs, 1980). A detailed description of the above methods follows. (Records must be kept of all disposals.)

9.1.1 Transfer of Waste to an Authorized Disposal Facility

Material may be transferred to an authorized commercial facility that will bury the waste on authorized property. All waste must be packaged and shipped according to the NRC's Title 10 and the Department of Transportation's Title 49, Code of Federal Regulations (CFR, 1980).

9.1.2 Release into a Sanitary Sewer System

Radioactive material may be released into a sanitary sewer system under the condition that the material is readily soluble or dispersible in water, and the amounts do not exceed the following limits:

a. Daily: Ten times the limits specified in Appendix C, 10 CFR 20, or the quantity of radioactive material that, when diluted by the average daily amount of liquid released into the sewer system results in an average concentration not greater than the amount specified in Appendix B, Table I, column 2, of 10 CFR 20. The greater of the two values determined above is permitted. The volume of sewage per day is approximately 1,000 liters per bed in a hospital and 500 liters per person in other institutions.

b. Monthly: The quantity of radioactive material that, when diluted by the average monthly amount of liquid released into the sewer system results in an average concentration not greater than the amount specified in Appendix B, Table I, column 2, of 10 CFR 20.

c. Yearly: A total of not more than 1 Curie of NRC licensed and other radioactive materials (e.g., accelerator produced).

Excreta from persons administered radioactive materials for medical diagnosis or therapy are exempt from the three limitations above.

A sample calculation involving soluble Iodine-131 disposal will illustrate the working of these disposal limits. The volume of sewage generated by an institution must be known; National Bureau of Standards Handbook #80 (1961) states that hospitals release 1×10^6 ml per bed per day. This example assumes a 200 bed hospital; i.e., one that would release 2×10^8 ml per day and 6×10^9 ml per month into the sewer system. The daily limit is the greater of the following two calculations: Ten times the value for Iodine-131 listed in Appendix C, 10 CFR 20, which is 1 μCi, i.e., (10) (1 μCi) = 10 μCi; or the sewage released per day times the soluble value listed in Appendix B, Table I, column 2, 10 CFR 20, $(6 \times 10^{-5}$ μCi/ml$)(2 \times 10^8$ ml) = 12,000 μCi. The calculations in this case show that the daily upper limit is 12,000 μCi. The monthly limit for soluble Iodine-131 for this 200 bed hospital is the value listed in Appendix B, Table I, column 2, times the monthly sewage volume or $(6 \times 10^{-5}$ μCi/ml$)(6 \times 10^9$ ml) = 360,000 μCi. The yearly limit for disposal of all radionuclides is 1 Ci. The reader is referred to the example and rules of Appendix B, 10 CFR 20, for disposal of mixtures and unknown radionuclides.

9.1.3 Burial

A licensee may be approved to bury radioactive mateial in the soil by the NRC or by an Agreement State. According to the NRC, radioactive materials may be buried upon approval in the soil as long as the burials are at least 4 ft. deep, 6 ft. apart, and not more than 12 burials are made in any year. The amount buried at any one location and time may not exceed 1,000 times the amounts listed in Appendix C, 10 CFR 20; thus, the amount of Iodine-131 that may be buried is (1000)(1 μCi) = 1,000 μCi. If mixtures of radionuclides are to be buried, the limit for each is reduced as illustrated in the NRC example at the end of Appendix C.

9.1.4 Other Disposal Methods

Methods of disposal other than those listed in 10 CFR 20 may be approved by the NRC if a specific request is made giving details such as concentrations and amounts that would be released. Incineration is one such "other method" that might be used in a nuclear medicine laboratory to dispose of animals containing radioactive materials used for research.

9.1.5 Storage

A fifth method, not given in 10 CFR 20, but acceptable to the NRC is storage of the radioactive material for decay and disposal as normal trash. At the present time, the licensee must have a "storage for decay" condition in the license to be allowed to do this. The recommended procedure used to determine what can be thrown away is to remove all shielding material and monitor gamma-ray emitting waste with a low-level survey instrument (e.g., G-M Counter); if background levels are indicated on the meter, then the

material can be disposed of after radioactive labels are removed. This method is useful for disposing of Tc-99m waste.

9.1.6 Disposal of Gases

Most nuclear medicine laboratories use Xe-133; it and other radioactive gases can be disposed of by storage and decay, or venting to the atmosphere. The amount of Xe-133 that can be released to unrestricted areas by dilution through exhaust hoods cannot exceed a yearly average of 3×10^{-7} μCi/ml of air. Up to a weekly (40 hr) average concentration of 1×10^{-5} μCi/ml of Xe-133 can be released to a restricted area such as a controlled access roof, but calculations must show to the licensing authority that subsequent concentrations reaching unrestricted areas will not exceed the 3×10^{-7} μCi/ml limit. According to the NRC, a "restricted area" means any area to which access is controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. The storage and decay method for Xe-133 is usually accomplished using commercially available activated charcoal traps. The disposal amounts specified by 10 CFR 20 and state regulations are upper limits only. Effort should be made to keep the amount of radioactive material released to the environment as low as reasonably achievable.

9.2 STATE REGULATORY AGENCIES

In the non-Agreement States, control of accelerator-produced radioactive material is the State's responsibility; while Agreement States have jurisdiction over both byproduct and accelerator-produced radionuclides. In general, most State regulations conform closely to those of the NRC. The reader is advised to consult a particular State's radioactive material control agency for information on individual State regulations.

REFERENCES

Code of Federal Regulations, Title 10 - Energy (10 CFR), Office of the Federal Register (Washington, D.C.: U.S. Government Printing Office), 1980.

Code of Federal Regulations, Title 49 - Transportation (49 CFR), Office of the Federal Register (Washington, D.C.: U.S. Government Printing Office), 1980.

National Bureau of Standards. NBS Handbook No. 80: A Manual of Radioactivity Procedures. Superintendent of Documents, NBS, Washington, D.C. (1961).

10. RADIATION ACCIDENTS AND EMERGENCIES

Vincent J. Sodd
Nuclear Medicine Laboratory, DEP, BRH, FDA
Cincinnati, Ohio

10.1 SPILLS AND BIOLOGICAL DISCHARGES

All spills and biological discharge of radioactive material should be reported to the Radiation Protection Officer and must be cleaned up immediately. It is accepted practice that surfaces should be kept as clean and free of radioactive contamination as practicable. The hazard from a contaminated surface can occur through resuspension of the radioactive material into the air and subsequent inhalation or by transfer from the surface to the hands and then from the hands to the mouth.

10.1.1 Monitoring Contamination

The most commonly used device for monitoring beta and gamma-emitting contamination is a G-M counter. Monitoring for contamination is done by slowly passing the detector probe over the suspected areas. It is helpful to have an audible signal from an earphone or loudspeaker attachment since it greatly aids in detecting small increases in count rate above the background rate. Also, it is easier to pay closer attention to the surface being monitored if a meter does not have to be watched. When monitoring loose contamination, the procedure of wipe testing can be used. A piece of filter paper is wiped over an area of approximately 100 cm^2 and is then counted.

10.1.2 Survey Frequencies

The frequency of radiation safety surveys at medical institutions is given in NRC Regulatory Guide 8.23 (NRC, 1981) as follows:

1. All elution, preparation, and injection areas should be surveyed daily with a survey meter and decontaminated if necessary.

2. Laboratory areas where only small quantities of radioactive material (less than 1 millicurie) are used should be surveyed monthly.

3. All other laboratory areas should be surveyed weekly.

4. The weekly and monthly surveys should consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/h.

   b. A series of smear tests to measure contamination levels. The method for performing smear tests should be sufficiently sensitive to detect the limits in Table 10.1 to one significant digit.

   c. Any air sample measurements necessary to determine compliance with 10 CFR 20.103 in cases where calculations alone are not sufficient (CFR, 1980).

Table 10.1. Limits for removable surface contamination in medical institutions[a] (NRC, 1981)

Type of surface	Type of radioactive material[b]		
	Alpha emitters (μCi/cm^2)	Beta or x-ray emitters (μCi/cm^2)	Low-risk beta or x-ray emitters (μCi/cm^2)
1. Unrestricted areas	10^{-7}	10^{-6}	10^{-5}
2. Restricted areas	10^{-6}	10^{-5}	10^{-4}
3. Personal clothing worn outside restricted areas	10^{-7}	10^{-6}	10^{-5}
4. Protective clothing worn only in restricted areas	10^{-6}	10^{-5}	10^{-4}
5. Skin	10^{-6}	10^{-6}	10^{-5}

[a] Averaging is acceptable over inanimate areas of up to 300 cm^2 or, for floors, walls, and ceiling, 100 cm^2. Averaging is also acceptable over 100 cm^2 for skin or, for the hands, over the whole area of the hand, nominally 300 cm^2.

[b] Beta or x-ray emitter values are applicable for all beta or x-ray emitters other than those considered low risk. Low risk nuclides include C-14, H-3, S-35, Tc-99m, and others whose beta energies are <0.2 MeV maximum, whose gamma or x-ray emission is less than 0.1 R/h at 1 meter per curie, and whose permissible concentration in air (see 10 CFR Part 20, Appendix B, Table 1) is greater than 10^{-6} μCi/ml.

10.1.3 Procedure for Dealing with Minor Spills and Contamination

Most spills in the nuclear medicine laboratory will involve millicurie quantities of short-half-lived radioactivitive materials. The following procedure can be used for dealing with this type of spill (Saenger, 1963):

1. Wash hands first if they are contaminated as a result of the accident. Put on rubber gloves to prevent contamination of the hands.

2. Cover liquid spill with absorbent material to limit spread of contamination. It is highly unlikely that a dry spill will occur in a nuclear medicine laboratory; but if encountered, it should be dampened to avoid spreading due to air currents, but carefully so as not to spread it unnecessarily.

3. If fans, ventilators, or air conditioners are operating in the area, they should be shut off; preferably, this should be done by someone not involved in the contaminated area.

4. Mark off contaminated area with chalk, marker, rope, etc., and restrict traffic to that area.

5. Do not allow anyone to leave contaminated area without first being monitored to be sure they are not contaminated.

6. Notify the radiation protection officer of the accident.

7. Start decontamination procedures as soon as possible. Cleaning agents normally used in the laboratory should be adequate. Start at the periphery of the contaminated area and work inward, reducing systematically the contaminated area.

8. Put all contaminated, disposal materials into plastic bags for disposal. Contaminated cleaning equipment such as brushes or mops should be stored in plastic bags until the radioactivity has sufficiently decayed before they are reused.

9. A survey meter or wipe tests should be used to monitor effectiveness of the decontamination procedure.

10. Area should be cleaned if the contamination level exceeds 200 dpm/100 cm^2 (NRC, 1980).

It is advisable to have a specific tray or cart prepared and set aside that is equipped with plastic bags and cleaning materials such as disposal towels, detergents, cotton swabs, and so forth, that can be used in case of a spill.

10.2 PERSONNEL CONTAMINATION

When radiopharmaceuticals are prepared in a well-ventilated hood, most contamination occurs on the outer surfaces of personnel. When body surfaces or clothing become contaminated, it is important that the contamination be removed as soon as possible to prevent its spread to other surfaces and to eliminate it as a source of internal contamination by way of ingestion, absorption, inhalation, and wound contamination. Washing with normal soap and detergent is the best initial approach. This should be followed by harsher methods when necessary using an abrasive soap or complexing agent. Clipping of the fingernails may remove a significant amount of contamination remaining on the hands after washing. Some degree of fixed contamination may occur; however, the maximum limits suggested for hands, body surfaces, or personnel clothing and shoes, for beta and gamma activity is 0.1 mrad/hr at 2 cm (Shapiro, 1974).

Personnel suspected as being contaminated should be monitored with a survey meter to identify problem areas. Clothing that is significantly contaminated should be removed and stored in plastic bags until the activity has decayed to an acceptable level of activity (approximately 200 dpm per 100 cm^2).

If contamination of the skin does occur, the decontamination procedure should not increase penetration of the radioactivity into the body by excessive abrasion of the skin. If contamination is in the area of a wound, a physician should supervise the decontamination operation. Wounds suspected of contamination should be irrigated profusely with tepid water and cleaned with a swab.

Decontamination of unabrased skin should be done initially with a mild soap or detergent and water. If necessary, a soft brush and/or an abrasive soap may be used. Other procedures using chemicals such as titanium dioxide paste are described elsewhere (Saenger, 1963).

Procedure for Personnel Decontamination:

1. Wet hands and apply soap or detergent.

2. Work up a good lather with plenty of water.

3. Wash lather into contaminated area 2-3 min being careful not to spread to other areas.

4. Rinse thoroughly with warm water but try to limit water to contaminated area.

5. Monitor the effectiveness of the procedure using a survey meter.

6. Repeat procedure 3-4 times, using soft brush if necessary, being careful to avoid scratching or erosion of the skin.

7. If the radiation level is still excessive, use a more abrasive soap.

8. Apply lanolin or other hand cream to prevent chapping.

10.3 MISADMINISTRATIONS

A misadministration in nuclear medicine is defined by the NRC in 10 CFR 35 (CFR, 1980) as the administration of a radiopharmaceutical other than the one intended; of a radiopharmaceutical to the wrong patient; or of a radiopharmaceutical by a route or in a quantity other than that prescribed. An incorrect quantity is a diagnostic dosage differing from the prescribed quantity by more than 50 percent; or of a therapeutic dose differing by more than 10 percent.

The NRC requires that when a misadministration involves a diagnostic procedure, the licensee shall notify, in writing, the referring physician and the appropriate NRC Regional Office within 10 days after the end of the calendar quarters in which they occur. When a misadministration involves any therapy procedure, the licensee shall notify, by telephone only, the appropriate NRC Regional Office, the referring physician and the patient or a responsible relative or guardian unless the referring physician informs the licensee either that he will inform the patient, or that, in his medical judgment, telling the patient or responsible relative or guardian would be harmful to one or the other. These notifications shall be made within 24 hours after the licensee discovers the misadministration. If the referring physician or patient cannot be reached, they shall be notified as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician: however, the licensee shall not delay medical care for the patient because of this. A written report written 15 days after the therapy misadministration shall be sent to the NRC Regional Office, the referring physician, and a copy shall be forwarded to the patient or patient's responsible person if either was previously notified verbally.

The written reports for misadministrations of either diagnostic or therapy dosages shall include licensee's name, the referring physician, a brief description of the event, the effect on the patient, and the action taken to prevent reoccurrence. The report shall not include the patient's name or other information that could lead to identification of the patient. The written report of the misadministration of a therapy dosage, shall state whether the licensee informed the patient or the patient's responsible person, and if not, why not.

10.4 HANDLING OF BODIES CONTAINING RADIOACTIVE MATERIAL

In general, handling of a body that contains only a tracer dose of any radioactive material, such as is likely to be used for diagnostic purposes, will not present a significant health hazard. Furthermore, diagnostic agents have short half-lives and a postponement of any procedure for a few days would greatly reduce any hazard that may exist. However, high levels of radioactive materials are administered to patients being treated for malignant disease. For example, at the present time the usual therapeutic dose of I-131 for treatment of thyroid cancer is approximately 100 mCi.

In any hospital the number of patients receiving these therapeutic dosages of radioactive material is small. Also, in principle, such therapy is not given to the moribund patients. Therefore, patients containing significant amounts of longer-lived radioactive materials ($t_{1/2} \geq 8$ days), rarely will require emergency surgery or will die. Hence, the problem of handling a radioactive body should be considered as a rare occurrence.

10.4.1 Surgery

If emergency surgery is to be performed on a patient who has recently received a therapeutic dose of radioactive material, the hazard will depend on the location of the radioactivity and the site of the operation. An appendectomy done on a patient given a therapeutic dose of I-131 which is essentially located in the thyroid area would not present as serious a problem as a patient containing radioactivity in the abdominal area. The identification of a particular patient as radioactive is the responsibility of the doctor in charge of the case (NCRP, 1970). While hospitalized, a distinctive label should be attached to the patient's chart stating the amount and kind of radioactive material administered and the time of administration.

Surgical procedures may have to be modified because of the presence of radioactivity. In general, regions of high activity should be avoided or shielded. Even rubber gloves are useful in this regard. Double thicknesses of surgical gloves can reduce the beta radiation from I-131 to about one third of the unshielded value. Other suggested procedures are given in NCRP Report No. 37 (NCRP, 1970).

10.4.2 Death

If a patient dies and contains more than 5 mCi of a radionuclide, the physician pronouncing death should affix a radioactivity label to the history accompanying the body when it is sent to the morgue (Quimby, 1960). It is also advisable that a specific form be available to attach to the death certificate, patient's chart and autopsy permission slip indicating the name and quantity of the radionuclide at a given date. A suggested form is shown in Figure 10.1. The physician in charge or the radiation protection officer should check the appropriate box before and after the procedure is carried out on the body. The radiation protection officer should be involved in the autopsy procedure if the content of radioactive material is over 5 mCi, and if over 30 mCi, the officer or his designee should be present for either the embalming or autopsy. A procedure for embalming and autopsy is given in the NCRP Report No. 37 (NCRP, 1970)

If the radioactive material is concentrated in specific tissues or body fluids, the radiation protection officer should indicate this to the person performing the post-mortem procedure so that these may be removed promptly, thus reducing the hazard. Radioactive fluids should be properly discharged down the drain without splashing to neighboring areas. Special care should be taken to prevent the floor of the morgue from becoming contaminated. It may be helpful to cover the floor with an absorbent material, underlaid with plastic, to provide a working area easy to decontaminate. Plastic aprons and rubber gloves should be worn to help prevent contamination of clothing or skin (NCRP, 1976).

10.4.3 Wounds Inflicted During Surgery or Autopsy

In cases where rubber gloves are cut or torn and radioactive material may be introduced into a wound, the gloves should be removed and the wound washed with large quantities of running water (NBS, 1951). The radiation protection officer shall be notified immediately to determine if residual contamination exists which warrants special decontamination measures (NCRP, 1970).

10.5 LOSS OF A SEALED SOURCE

Because most radioactive materials used in nuclear medicine are administered as liquids, and less often as gases, the possibility of losing a sealed source is rare unless therapy is also practiced in the same location. Under most circumstances, sources will leave the preparation or hot lab only after they have been prepared for administration. It is expected that these prepared dosages will be handled in a secure manner, just as would any pharmaceutical in a hospital, so that they could not fall into unauthorized possession. However, if a

capsule, vial, syringe, etc., containing radioactive material is lost, a general outline of the procedure to be used is the following:

1. Call the radiation protection officer.

2. Do not allow patient, or other persons, materials such as apparatus, bed linens, bandages, etc., to leave the suspected area until they have been surveyed with a radiation counter.

3. Survey the room to be sure the source is not on the floor or furniture.

4. Survey the drain trap of any accessible plumbing facility.

5. Survey the garbage dump, incinerator and other possible means of disposal.

REFERENCES

Code of Federal Regulations, Title 10-Energy (10 CFR). Office of the Federal Register. (Washington, D.C.: U.S. Government Printing Office), 1980.

National Bureau of Standards. NBS Handbook No. 48: Control and Removal of Radioactive Contamination in Laboratories. Superintendent of Documents, NBS, Washington, D.C. (1951).

National Council on Radiation Protection and Measurements. NCRP Report No. 37: Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides. NCRP, Washington, D.C. (1970).

National Council on Radiation Protection and Measurement. NCRP Report No. 48: Radiation Protection for Medical and Allied Health Personnel. NCRP, Washington, D.C. (1976).

Quimby, E.H. Safe Handling of Radioactive Isotopes in Medical Practice. The MacMillan Co., New York (1960).

Saenger, E.L. Medical Aspects of Radiation Accidents. (Washington, D.C.: U.S. Government Printing Office) 1963.

Shapiro, J. Radiation Protection - A Guide for Scientists and Physicians. Harvard University Press, Cambridge (1974).

U.S. Nuclear Regulatory Commission. NRC Regulatory Guide 10.8: Guide for the Preparation of Applications for Medical Programs. NRC, Washington, D.C. (1980).

U.S. Nuclear Regulatory Commission. NRC Regulatory Guide 8.23: Radiation Safety Surveys at Medical Institutions. NRC, Washington, D.C. (1981).

NOTICE TO AUTOPSY SURGEON AND TO FUNERAL DIRECTOR
OF BODY CONTAINING RADIOACTIVE MATERIAL

Attach to death certificate, patient's history, and to autopsy permission slip, if there is to be one.

- This body contains between 5-30 mCi of radioactive material. If an autopsy is to be done, the radiation protection officer should be consulted as to any precautions. If the funeral director is to employ only standard injection embalming procedures, no special precautions are necessary.

- This body contains more than 30 mCi of radioactive material. If an autopsy is to be performed, the radiation protection officer or his designee should be present. The funeral director should observe the following precautions:

_____

_____

_____

Signed:
Date:
Radiation Protection Officer's Name:
Phone Number:

Figure 10.1. A typical form to accompany body of individual who died containing radioactive material.

*U.S. GOVERNMENT PRINTING OFFICE: 1981-0-361-177/213

FDA 81-8054 11th Annual Conference on Radiation Control - Radiation: Minimizing Exposure; Optimizing Use.

FDA 81-8070 Bureau of Radiological Health Publications Subject Index (supersedes FDA 80-8070, May 1980) (PB 81-149478, $5.00).

FDA 81-8136 Optical Radiation Emissions from Selected Sources: Part I - Quartz Halogen and Fluorescent Lamps (GPO 017-015-00177-6, $6.50) (PB 81-139693, mf only).

FDA 81-8139 Quality Assurance in Diagnostic Ultrasound - A Manual for the Clinical User (GPO 017-015-00179-2, $4.00) (PB 81-139727, mf only).

FDA 81-8141 Quality Assurance in Diagnostic Radiology and Nuclear Medicine - The Obvious Decision (PB 81-164477, $14.00).

FDA 81-8142 Use of Photographic Film to Estimate Exposure Near the Three Mile Island Nuclear Power Station (PB 81-183402, $6.50).

FDA 81-8143 Procedures for Evaluating Nonperturbing Temperature Probes in Microwave Fields (GPO 017-015-00189-0, $2.75) (PB 81-205882, mf only).

FDA 81-8144 Assembler's Guide to Diagnostic X-Ray Equipment.

FDA 81-8146 Radiographic Film Processing Quality Assurance: A Self-Teaching Workbook (GPO 017-015-00180-6. $4.00) (PB 81-163974, mf only).

FDA 81-8147 Quality Assurance in Diagnostic Radiology: A Guide for State Program Implementation (PB 81-175747, $9.50).

FDA 81-8150 The Correlated Lecture Laboratory Series in Diagnostic Radiological Physics (GPO 017-015-00184-9, $4.50)(PB 81-183444, mf only).

FDA 81-8151 A Feasibility Study of the Biological Effects of Fallout on People in Utah, Nevada, and Arizona (PB 81-187692, $5.00).

FDA 81-8152 Annual Report of the Division of Biological Effects, Bureau of Radiological Health - Fiscal Year 1979 (PB 81-187155, $11.00).

FDA 81-8153 An Evaluation of Radiation Emission from Video Display Terminals (GPO 017-015-00187-3, $4.25) (PB 81-198483, mf only).

FDA 81-8155 A Practitioner's Guide to the Diagnostic X-Ray Equipment Standard (GPO 017-015-00185-7, $1.25).

FDA 81-8156 Symposium on Biological Effects and Measurement of Light Sources (GPO 017-015-00191-1, $6.50) (PB 81-214223, mf only).

FDA 81-8157 An Intercomparison of Nuclear Medicine, Ultrasonography, and Computed Tomography in the Diagnosis of Liver Disease: A Retrospective Study (PB 81-199044, $6.50).

FDA 81-8158 Background Material for the Development of the Food and Drug Administration's Recommendations on Thyroid-Blocking with Potassium Iodide (GPO 017-015-00188-1, $2.25) (PB 81-205361, mf only).

FDA 81-8161 BRH Routine Compliance Testing for Diagnostic X-Ray Systems (PB 81-201501, $15.50).

FDA 81-8162 Handbook of Computed Tomography -X-Ray Spectra (PB 81-295890, $11.00).

FDA 81-8163 Airborne Ultrasound: Measurement and Possible Adverse Effects (GPO 017-015-00193-8, $2.00).

FDA 81-8164 Calculation Programs for Routine Compliance Testing of Diagnostic X-Ray Systems (PB 81-200503, $8.00).

FDA 81-8166 Third International Radiopharmaceutical Dosimetry Symposium (October 1980 (GPO 017-015-00194-6, $11.00) (PB 81-233090, mf only).

FDA 81-8169 Pilot Study of Social Security Administration Disability Claims (SSADC), by Selected Diagnosis and Qualified Radiation Exposure.

FDA 81-8170 Effects of Ionizing Radiation on the Developing Embryo and Fetus: A Review (GPO 017-015-001989, $5.50).

FDA 81-8171 Self-Assessment and Competency Assurance Education in Diagnostic Radiologic Technology: Final Report (September 30, 1977 to April 30, 1980) (PB 81-237448, $6.50).

FDA 81-8178 Procedures to Minimize Diagnostic X-Ray Exposure of the Human Embryo and Fetus.

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Bureau of Radiological Health
Rockville, Maryland 20857

THIRD-CLASS BULK RATE
U.S. Postage Paid
PHS
Permit G29

OFFICIAL BUSINESS

ADDRESS CORRECTION REQUESTED
Return this sheet to above address, if you do NOT wish to receive this material ☐ or if change of address is needed ☐ (indicate change, including ZIP code).

FDA 1906 75 1981
YEARS
PIONEERS IN CONSUMER PROTECTION

AN EQUAL OPPORTUNITY EMPLOYER